INCIDENCE OF LOW BACKACHE IN RELATION TO ANATOMICAL VARIATIONS OF SACRAL HIATUS

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To my husband and my parents

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ABSTRACT

Lumbago is pain in the area amid the costal margin and inferior gluteal folds. Globally it is the fourth 'most common cause' of disability associated years. Heavy weight lifting, twisting, bending, high BMI and sacral developmental defects have been associated with high frequency of low backache. The sacral hiatus is an arched gap on the dorsal surface of the sacrum. It is a continuation of the sacral canal that contains the sacral nerve, coccygeal nerve, fibrous tissue, fatty tissue and filum terminale. Variations of the sacral hiatus are related to increase in risk of iatrogenic problems in caudal procedures as well as mechanical low back pain.

The study was conducted to compare the shape, level of apex, level of base, length, anteroposterior, and transverse diameters of hiatus sacralis between cases with low backache and control subjects, compare the incidence of variations of sacral hiatus between males and female cases, compare the demographics and patient characteristics between cases and controls, compare the hiatal variations, demographics and patient characteristics within cases, and determine the relationship of the anatomical variations, demographics and patient characteristics with low back pain.

The study was conducted at PNS Shifa hospital and Advanced Radiology Clinic, Karachi after the approval of synopsis (Appendix A) and ethical approval from BUMDC and Advanced Radiology Clinic (Appendix B). Eighty nine cases and eighty nine controls were enrolled by non-probability convenient sampling. The cases were recruited from outpatient departments of rehabilitation medicine, orthopedic surgery and emergency medicine based on presenting complaints and examination while controls were asymptomatic patients presenting to the radiology department from other specialties for the purpose of medical review. Individuals meeting the inclusion criteria after signed informed consent (Appendix C) were included in the research project. Anteroposterior and lateral radiographic images of the lumbosacral spine were obtained through the Toshiba Rotanode X-Ray machine. Using the anteroposterior radiographs, the hiatus was identified inferior to the median sacral crest. The shape, level of apex and level of base were identified on observation. The length was measured from the hiatal apex to a point at the center of its base. The anteroposterior diameter was measured at the apex of the hiatus in the lateral view and the width was measured between the sacral cornua. The participants' height and weight were measured using the stadiometer. Information regarding demographics and factors related to low back pain were recorded in the subject evaluation proforma (Appendix D).

A total of 179 participants were evaluated. High possibility of “low back pain” was found with hiatal shapes inverted ‘U’ and ‘M’, hiatal apex at S1 or S2, base at S3, hiatal length (more than 30mm), transverse width (more than 13mm) and variations in the anteroposterior diameter. Predominance of back pain was observed in married individuals. Prevalence of symptoms was high among cases with no exercise. High incidence was observed among house wives, office workers, and field workers. House work, prolonged standing and bending were most common aggravators of back pain. Association between increased BMI and weight with occurrence of low back pain was established.

The current study concluded that there is an association between the variations of hiatal anatomy and low back pain. Possibility of low back pain is present in hiatal shapes inverted ‘U’ and ‘M’, apex above S3, base at S3 or above, long, deep and wide hiatus. A high BMI, sedentary lifestyle, occupation and physical workload are also significantly related to low back pain.

KEYWORDS: Sacral hiatus variations, measurements, x-ray, sacral anatomy, back pain

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LIST OF ABBREVIATIONS

S. NO	ABBREVIATION	STANDS FOR
1.	AP	Anteroposterior
2.	BMI	Body Mass Index
3.	BPI	Brief Pain Inventory
4.	CLBP	Chronic Low Back Pain
5.	C.I	Confidence Interval
6.	cm	Centimeter
7.	CPU	Central Processing Unit
8.	CR	Computed Radiography
9.	CT	Computed Tomography
10.	CSF	Cerebrospinal Fluid
11.	FDA	Food and Drug Administration
12.	HRQoL	Health Related Quality of Life
13.	Kg	Kilograms
14.	kVp	Kilo Voltage peak
15.	mAs	milli Ampere second
16.	LAT	Lateral
17.	LS	Lumbosacral
18.	mm	Millimeters
19.	MPa	Mega Pascal
20.	MPQ	McGill Pain Questionnaire
21.	MRI	Magnetic Resonance Imaging
22.	NICE	National Institute of Health and Care Excellence
23.	NSAIDS	Non-steroidal anti-inflammatory drugs
24.	ODI	Oswestry Disability Index
25.	O.R	Odds Ratio
26.	PACS	Picture Archive and Communication System

27.	Pax	Paired box genes that encode DNA transcription factors
28.	PSIS	Posterior superior iliac spine
29.	QBPDS	Quebec Back Pain Disability Scale
30.	RMDQ	Rolland Morris Disability Questionnaire
31.	S (1-5)	Sacral vertebra
32.	SD	Standard Deviation
33.	SH	Sacral Hiatus
34.	SBO	Spina bifida occulta
35.	SSBO	Sacral Spina Bifida Occulta
36.	WHO	World Health Organization

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CHAPTER 1

INTRODUCTION

The sacrum is a curved, triangle shaped bone at the lower end of the vertebral column. It is a bridge between the two hip bones that are connected superiorly with the lumbar spine and inferiorly with the coccyx. It has been regarded as the “keystone” of the body and was considered sacred by ancient civilizations (Nastoulis, Karakasi, Pavlidis, Thomaidis, & Fiska, 2019).

The sacrum is formed by five vertebrae which are fused in the midline. Its base is the upper surface of the 1st sacral vertebra at the level of the sacroiliac joint. The base curves downwards and forwards at an angle of 30˚ or more to taper off forming the apex of the sacrum. Each sacral vertebra consists of body, laminae, transverse and articular processes. The fusion of the vertebral bodies creates a smooth, concave pelvic surface. Ventrally this smooth surface roofs the posterosuperior wall of the pelvic cavity. Posterior to the vertebral bodies, the vertebral canal continues to become the “sacral canal”. The laminae of the sacral vertebrae fuse dorsally, covering the contents of the sacral canal and form the median sacral crest. Lamina of 4th and often the 5th sacral vertebrae however, fail to fuse leaving a gap through which the filum terminale exits to attach to the coccyx. On the other hand the articular processes (inferior) of the S5 extend downward on either side of this opening and form the sacral cornua. The ‘articular processes’ of the remaining sacral vertebrae combine and form an intermediate sacral crest. Furthermore, tips of the transverse processes unite to form the lateral sacral crest (Fig 1A). Lateral to the median sacral crest are the sacral foramina. These are present on the dorsal and pelvic surfaces of the sacrum. The sacral nerves exit the sacral canal through these foramina (Moore, Dalley, & Agur, 2018). The intermediate layer of muscles of the back is also attached to the dorsum of the sacrum. The gluteus maximus is attached just below the sacroiliac joint. The multifidus, sacrospinalis, and erector spinae muscles arise from the medial aspect of the sacral grooves. The latissimus dorsi and occasionally inferior coccygeus muscles surround the other muscles (Fig 1.1) (Cheng & Song, 2003). The sacral hiatus is a natural arched gap present in the

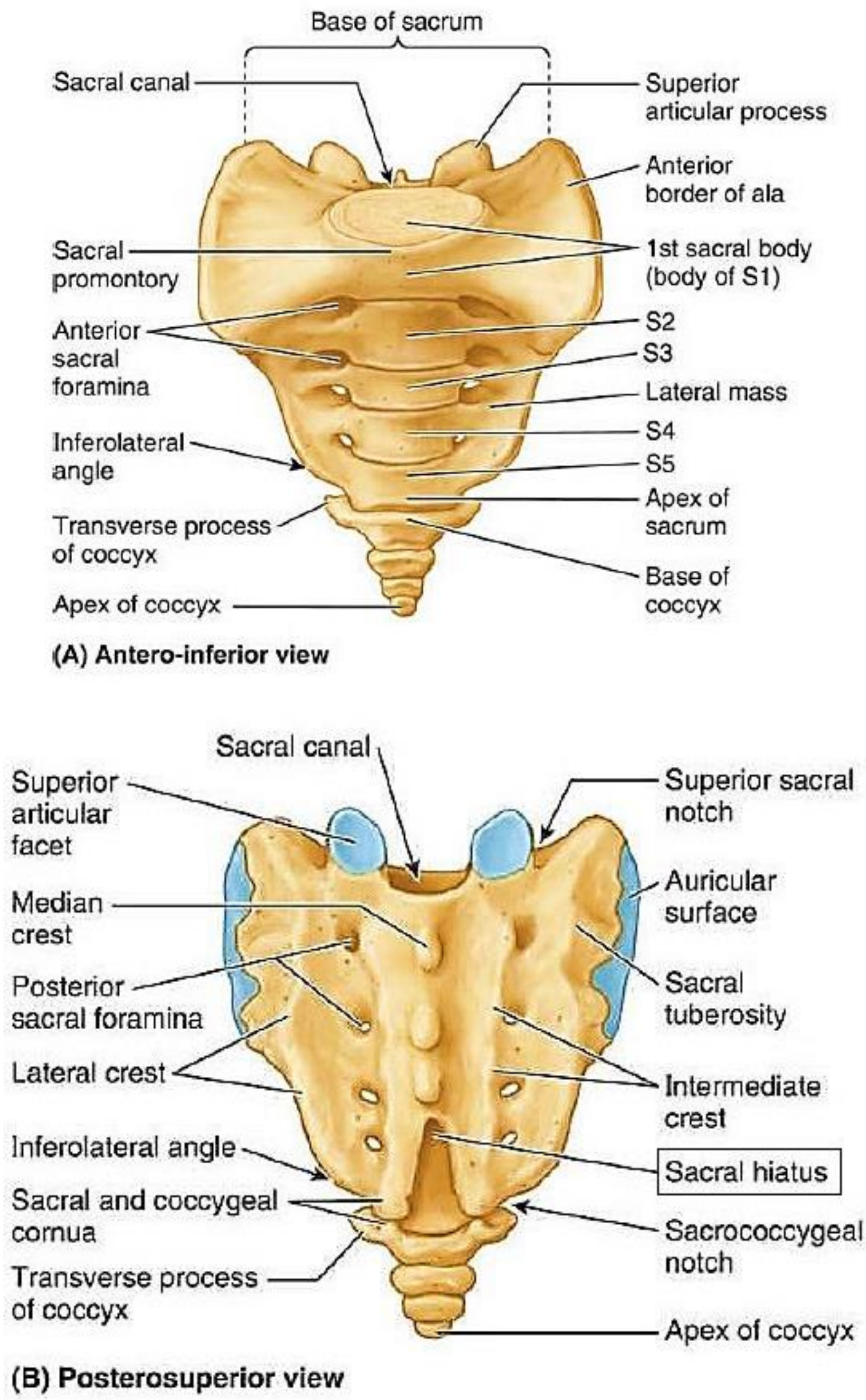


Fig. 1 (A) Sacrum Anterior View showing sacral vertebrae and foramina (B) Sacrum Dorsal view showing the sacral hiatus (Moore et al., 2018)

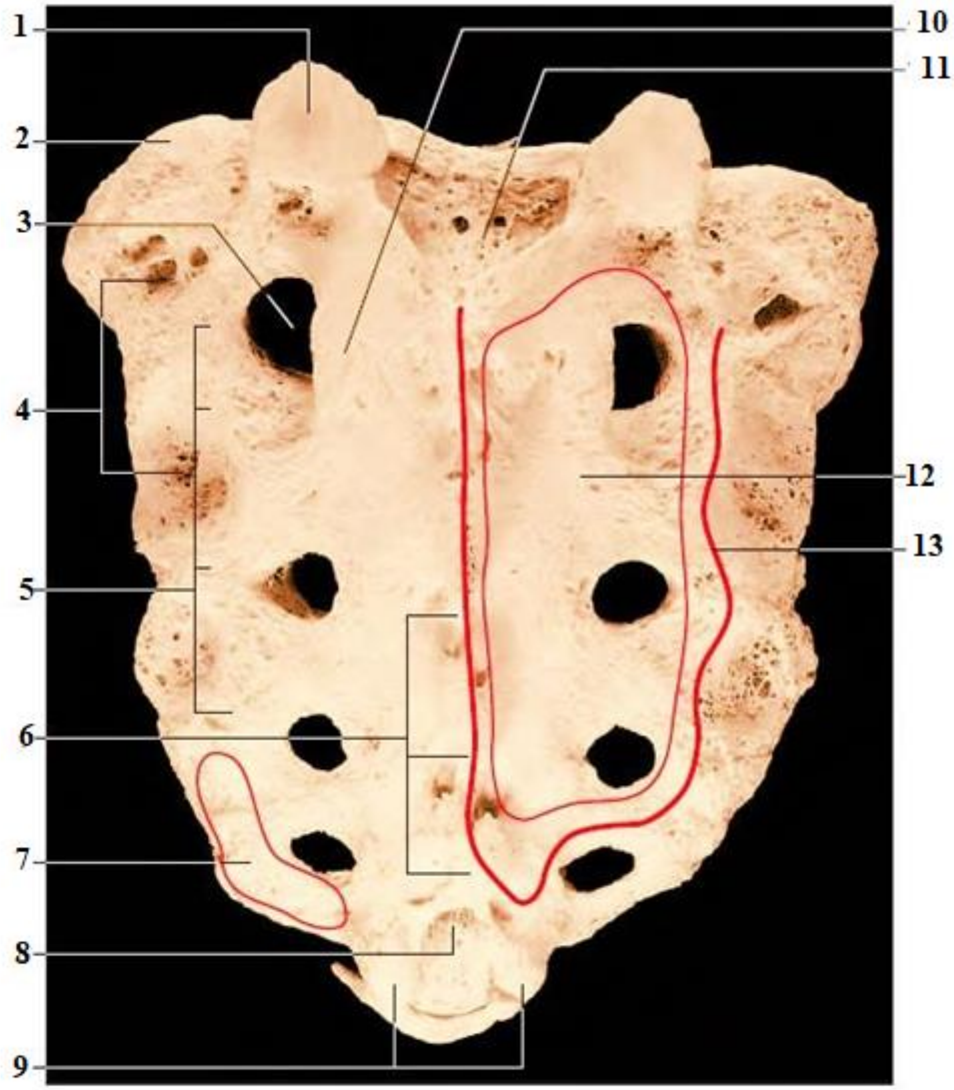


Fig 1.1 Dorsal surface of sacrum with muscle attachments

Key: 1) S1 & its articular facet (superior); 2) sacral ala; 3) dorsal sacral foramen (1st); 4) site of sacroiliac ligament; 5) lateral sacral crest & transverse tubercles; 6) median sacral crest & spinous processes; 7) gluteus maximus insertion; 8) hiatus sacralis; 9) sacral cornua; 10) intermediate sacral crest & articular process (inferior); 11) anterior wall of sacral canal (dorsum of S1 body); 12) multifidus attachment; 13) attachment of erector spinae aponeurosis (thin line)

(Standring et al., 2016)

posterior wall of the “sacral canal” (Fig 1B). The natural defect is created by non-union of the lamina of the S4 or S5 in the midline. The hiatal opening is closed by fibrous tissue that forms the sacrococcygeal ligament. It is covered by subcutaneous tissue and skin. The inverted U or V shapes are considered normal. The hiatus normally consists of tip (apex) and a bottom (base) containing the filum terminale, roots of 5^{th} sacral and coccygeal nerves. Imaging of the lumbosacral and pelvic regions provides insight about the hiatal structure. It can be identified inferior to the median sacral spine on the anteroposterior views of the sacrum (Asghar & Naaz, 2013).

Appearance of the hiatus varies according to the method of study. On radiographs it has the appearance of a radiotransparent area at the lower end of the sacrum (Fig 1.2). On ultrasound it is described as a hypoechoic region between the hyperechoic sacral cornua (Fig 1.3) (Macchi, Porzionato, Morra, Stecco, & De Caro, 2011). Observed hiatal characteristics are its shape, apex, base, length, transverse diameter (width) and depth. Length of sacral cornua, distances from the hiatal tip to S2 foramen and measurements from the hiatal tip to the superolateral crests are used for identification of the hiatus sacralis clinically. The distance from the tip of the hiatus till the end of the dural sac is also important (Shinde & Shirbadgi, 2016).

Caudal position of the sacral hiatus has made it an important portal for access to the epidural space without causing significant side effects. With development of innovative minimally invasive procedures in anesthesia and spinal surgery, use of sacral hiatus has become more popular. It is currently applied for regional anesthesia in pediatric cases, fluoroscopy, thecaloscopy, anorectal surgery, hernia repair, circumcision and steroid analgesia for chronic low back or pelvic pain. Individual and racial variations of the hiatus are common and exert a powerful impact on success of regional anesthesia as well as minimal invasive surgical procedures of the spine. Deficient dorsal wall of sacral canal has been observed in cases of “non-specific low back pain”. Dry bone studies have revealed that variation in anatomy of the dorsal wall of the sacral hiatus exists in patients suffering from “non-specific low back pain”. It has been inferred that such variations result in decreased surface area for the attachment of back muscles thereby causing muscle spasm which is experienced by the patient as “low back pain” (Kumar, Nayak, Potu, & Pulakunta, 2009).

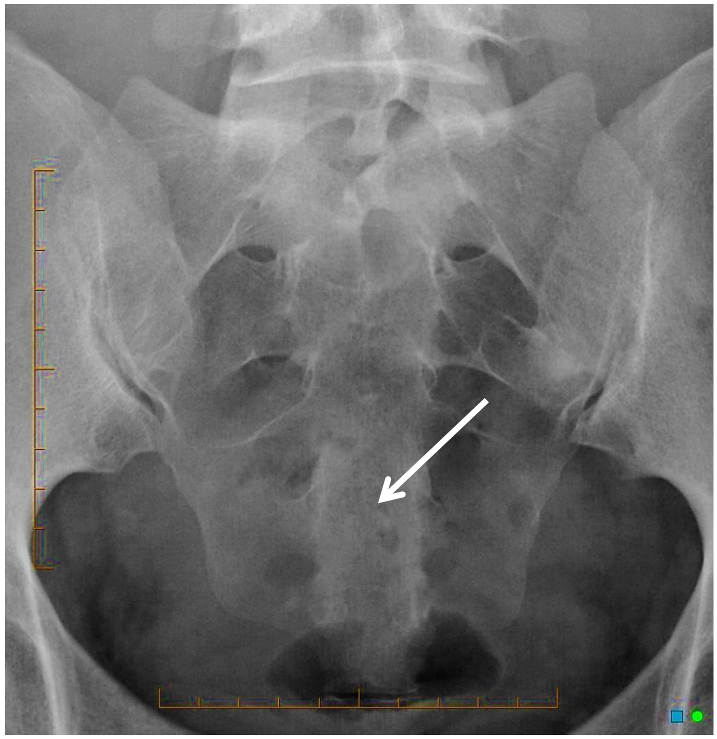


Fig 1.2 Anteroposterior view of sacrum with sacral hiatus (arrow)
(Case courtesy of Assoc Prof Frank Gaillard, Radiopaedia.org)

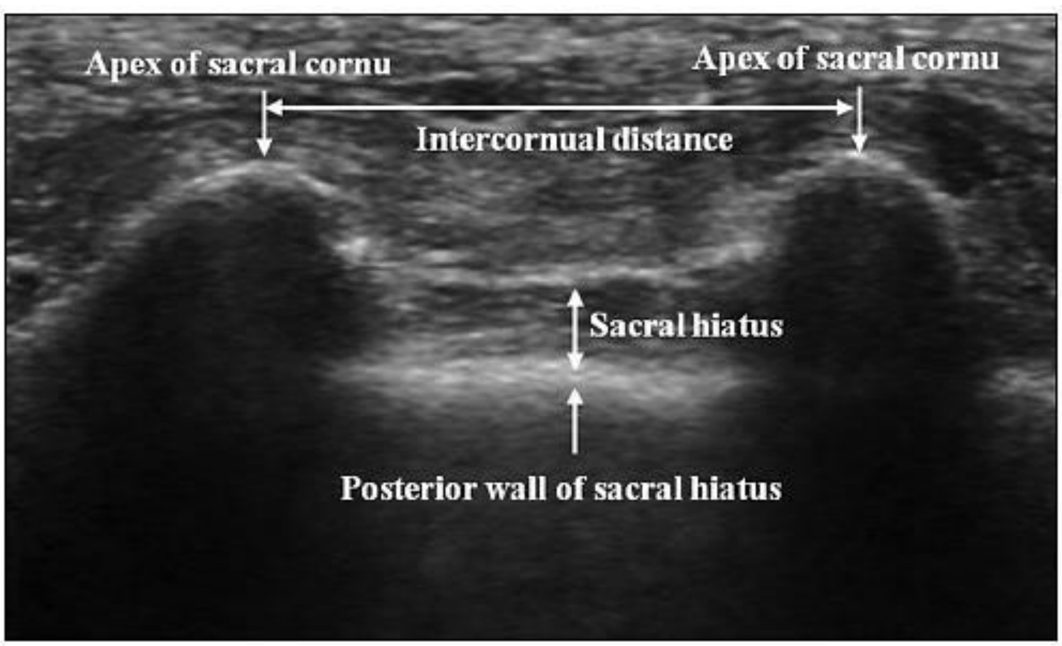


Fig 1.3 Ultrasonographic appearance of sacral hiatus (Park, Kwon, & Cho, 2015)

Development of the spinal cord and vertebra begins in the 3rd week of gestation. These processes are closely interlinked. In the 3rd week the human embryo consists of three germ layers; ectoderm, mesoderm and endoderm. All the structures of the embryo are formed during this period from these layers. The spinal cord development is initiated by inductive influences from the notochord. It influences the ectodermal cells to form the neural plate which infolds to form the neural tube which forms the brain and spinal cord. The spinal cord initially extends as far as the 2nd coccygeal vertebra. Relative shortening of the spinal cord occurs, however the meninges remain attached to the coccyx forming the filum terminale. Defects in relative shortening or canalization of the spinal cord result in lumbosacral lipoma, lipomeningocele and tethering of the cord by thickened filum terminale (Ko, 2019). Concomitantly, development of the notochord and neural tube induces surrounding mesoderm to thicken and form paraxial mesoderm. It is arranged as 2 longitudinal columns on the dorsolateral surface of the embryo. Towards the end of the 3rd week, paraxial mesoderm columns in the trunk form cuboid blocks called somites. These structures first appear in the occipital region around day 20 of embryonic development. Somites grow in a craniocaudal fashion to extend as far as the coccygeal region. The end of the 5th week is characterized by 42-44 pairs of somites. Somites differentiate into “sclerotome” and “dermomyotome” components, each with a different purpose. Mesenchymal cells of the sclerotome form the vertebral column. Defective fusion of the embryonic vertebral arch results in “spina bifida”. If the defect is closed and covered by thick membrane or skin, it is known as “spina bifida occulta” (Fig1.4.1 & 2) (Moore, Persaud, & Torchia, 2016).

“Low Back” is the area extending from the last rib till the inferior gluteal fold. Discomfort in the lower back is described as aching and muscular rigidity localized inferior to the costal margin and superior to the gluteal folds, with or without leg pain (sciatica) (Chou, 2011). Low backache is one of the most common illnesses associated with individual suffering. In developed countries, the lifetime prevalence is estimated at 60-70%. One year prevalence of low back pain is 15-45%. In adults there is a 5% incidence per year (Holy, Brooks, Blyth, & Buchbinder, 2014). Low back pain is linked with biological, psychological and social factors. These influences can prolong or worsen the clinical presentation (Bevers, Watts, Kishino, & Gatchel, 2016).

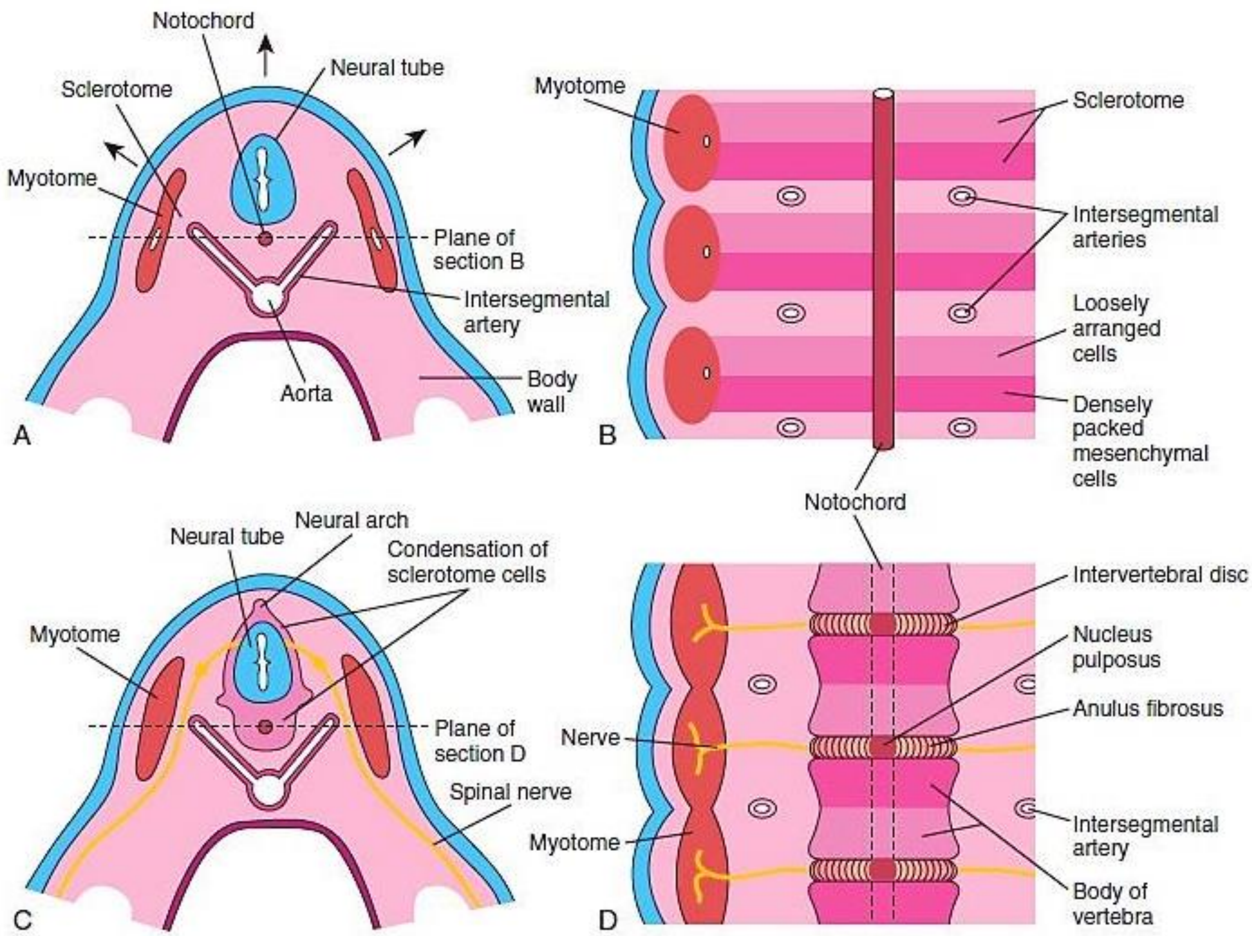


Fig 1.4.1 Development of vertebra (Moore et al., 2016)

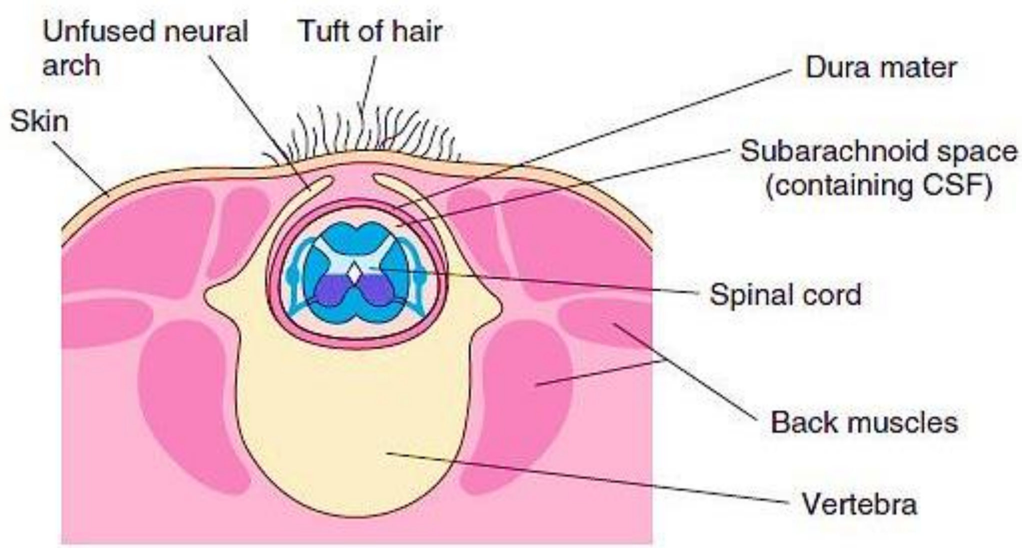


Fig 1.4.2 Developmental defect; spina bifida occulta (Moore et al., 2016)

1.1 ANATOMY OF SACRAL HIATUS

The hiatus sacralis is a gap on the posterior surface of the sacrum. It is bordered laterally by the sacral horns (cornua). Above, the hiatus leads into the “sacral canal” which is in continuity with the “vertebral canal” (Fig 1B). Morphometric analyses have described the metric and non-metric parameters of the hiatus. The observable characteristics of the hiatus such as its shape, apex level and base level are categorized as non-metric. The metric parameters are the measurements of hiatal length, width, and anteroposterior diameter. Other measurements include the distance between the superolateral crests, distance from the hiatal tip to the superolateral crests, distance from hiatal tip to 2nd sacral foramen and the distance from bottom of the hiatus to 2nd sacral foramen (Senoglu et al., 2005).

1.1.1 Shape

On gross examination the opening of the hiatus is usually trilateral. The top is directed superiorly, while the bottom inferiorly. Although variants are not uncommon, most frequently it is “triangular” (Sinnatamby, 2011). Variants of its shape have been observed during cadaveric dissection, radiographic imaging, epidural anesthesia, fluoroscopy, or spinal surgery. The most commonly documented shapes include the inverted “U” and “V”. Variants such as irregular, dumbbell, bifid and M shapes have also been observed. Absent sacral hiatus is reported in association with “spina bifida occulta” (Pundge, Mane, & Joshi, 2017).

1.1.1.1 Variants of Hiatal Shape

(a) Irregular

It is a hiatus characterized by lateral boundaries that are not completely smooth or uniform. Sometimes there is a uniform projection (Fig1.5 C).

(b) Bifid

It is an aperture in the dorsal wall of the sacrum in which the lamina is open above the fused part (Fig 1.5 D).

(c) Dumbbell

Shape of hiatus formed in which bony projections from both sides of the opening are present at more or less the same level (Fig 1.5 E).

(d) M

Shape in which there is a downward projection in the middle that indents the apex of the hiatus (Fig 1.5 F).

(e) Absent Sacral Hiatus

It is also known as agenesis of the sacral hiatus. It occurs in cases when bony overgrowth and fusion of all sacral laminae obliterates the hiatal opening completely.

1.1.1.2 Significance

The variety in the shapes of the hiatus can cause hindrance in needle insertion during caudal epidural anesthesia. Due to the overgrown bony margins and asymmetrical shape, the epidural needle may even break. In such shapes caudal epidural block is discouraged (Vedapriya & Rajasree, 2013).

1.1.2 Apex

The hiatal summit is marked at the end of the "sacral canal". It is described with reference to the sacral vertebra. Frequently it is visible at S4 level. Individual variation of its location is however prevalent. The highest observed level of the apex is S2 and the lowest level identified is S4. The dural sac normally ends at the level of S2. When situated at a higher level, the proximity between the apex and dural sac decreases increasing the probability of dural puncture during intervention (Kao & Lin, 2017).

The relation of the apex to the dural sac can be identified without use of radiographic equipment by forming an inverted triangle on the dorsal surface of the sacrum. The base of this triangle is the measured distance between the superolateral crests of the sacrum. These crests are present at the level of the "posterior superior iliac spine" (PSIS). The limbs (right and left) of this triangle are the measurements between the hiatal tip and the sacral crests (Kim, Park, Cho, & Moon, 2014).

Identification of the apex is dependent on the individual factors such body mass index, age, gender, and spinal malformations. Among these body weight has been associated with difficulty in identification of the hiatus. It is ascertained that with an increase in the weight, identification of the apex becomes difficult and in some cases impossible by palpation because of the excess fat around the sacral region. In overweight individuals fluoroscopic

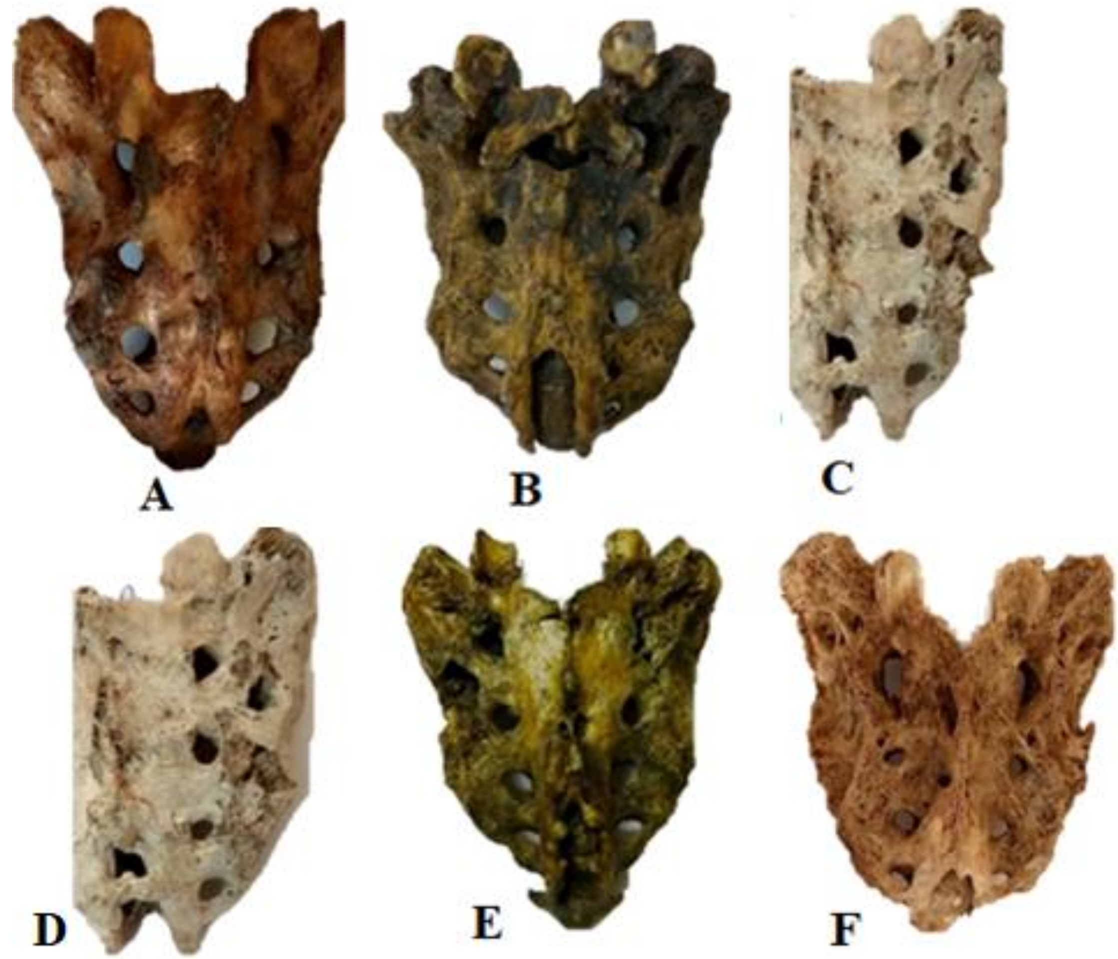


Fig 1.5 Variants of sacral hiatus shape

Key: (A) Inverted V; (B) Inverted U; (C) Irregular; (D) Bifid; (E) Dumbbell; (F) M shape (Vedapriya et al., 2013)

or ultrasound guidance is required for accuracy (Barham & Hilton, 2010).
In 73% of Pakistani sacra, the apex lies at the level of the 4th sacral vertebra. In 24% of the population it is seen at the level of 3rd sacral vertebra, making it the 2nd most common site. Furthermore, in 2% of sacra the apex level is seen at 5^{th} and in 1% at the 2nd sacral vertebra (Ali, Qureshi & Ali, 2015).

1.1.3 Base

The base is the inferior part of the hiatus. It is an area between the sacral horns (cornua). These are derived from the inferior sacral vertebral articular processes. Racial, regional and individual variations affect the location of the hiatal bottom. The sacral and coccygeal vertebrae are used as a landmark to identify the level at which it is observed. In dry bone studies most frequently, it has been observed to lie at the level of coccyx, S5 and S2 (Fig 1.6(2)). Although the apex is the preferred site of entry into the sacral canal, the base can be used as a safer alternative in complicated cases (Bagheri & Govsa, 2017). In 96% of the Pakistani sacra, the base of the hiatus has been seen at level of S5 and in 4% at coccygeal vertebrae (Ali et al., 2015).

1.1.4 Length

It is one of the commonly measured parameters of significance. It is defined as the measured distance of the sacral hiatus in a vertical plane. Measurement is obtained manually by vernier calipers or digitally with specialized software in metric units (mm). The anatomical references used for this parameter is the apex of the hiatus to another point at the center of the hiatal base (Fig 1.6(1)). In the clinical setting and cadaveric dissection the length of the hiatus has been accurately measured with radiographic imaging such as ultrasound, CT scan and MRI. To reduce radiation exposure and expenditure, the X-Ray pelvis and lumbosacral spine can also be used to observe it as an alternative to using dry human sacra. Determination of the length of the hiatus before intervention ensures patient comfort and safety during procedures involving the hiatal area (Mustafa, Mahmoud, El Raouf, & Atef, 2012). The length of the hiatus is directly related to the length of the sacrococcygeal ligament. This has been noticed to cause failure of regional block. Failed “caudal epidural block” has been observed with hiatal lengths of 16mm (Kim et al., 2014).

The hiatus is categorized as long or short based on its summit. A long hiatus has been observed in sacra with sacral malformation such as “spina bifida occulta”. In the Pakistani sacra long sacral hiatus is present in 24% of sacra. Amongst these, a long hiatus terminating at S2 has been seen in 1% and at S3 in 23%. On the contrary, if the level of the top is observed at S5, it is considered as a short sacral hiatus. 2% of Pakistani population has a short sacral hiatus (Ali, Azeemi, & Shoukat 2014). On average the hiatus is 21.73$\pm$8.92mm long (Singh, Gupta, & Singh, 2018).

1.1.5 Width

It is recognized as the intercornual or transverse distance of the hiatus. It is one of the significant parameters measured at the bottom of the hiatal opening. Identification of the base is crucial for measuring the width. The tips of the cornua are used to measure the distance because they form the lateral boundaries of the opening (Fig 1.6(2)). Measurement of the width can be ascertained on dry sacra with vernier calipers or on radiographic images with specialized software. The average transverse diameter of the hiatus is 11.59$\pm$3.25mm (Singh et al., 2018). The width of the hiatus is used to determine capacity of the hiatus for an epidural needle or epiduroscopic equipment (Kilicaslan et al., 2015).

1.1.6 Antero-posterior Diameter

It is one of the most significant parameters of the sacral hiatus. It is alternatively referred to as the depth of the hiatus. It is measured from the tip of the hiatus to the posterior surface of the fused vertebral bodies. It is commonly measured in morphometric studies of dry human sacra however lateral lumbosacral radiographs, CT scan and MRI images are also utilized.
The dimensions are crucial for determining the depth of the hiatal entrance as it leads into the sacral canal. A depth of less than 3mm is known to cause failure of caudal epidural anesthesia. Mean diameter of the hiatus ranges from 4.6$\pm$2mm to 6.1$\pm$2.1mm. Variations of the anteroposterior diameter are dependent on how much of the fourth sacral spine and lamina are present. Reduced hiatal diameter has been observed with advancing age (Park et al., 2015).

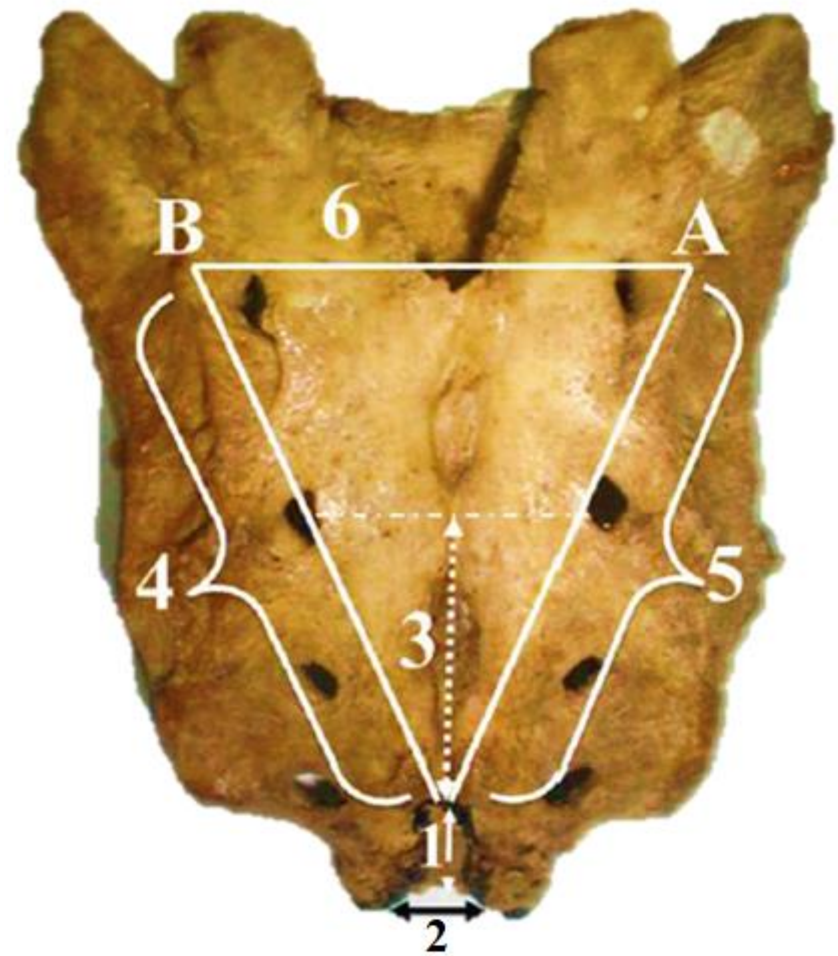


Fig 1.6 Dorsal surface of human adult dry sacrum with measured parameters of sacral hiatus: (1) Length of sacral hiatus; (2) width of the hiatus; (3) distance between apex and second sacral foramen; (4) distance between apex of hiatus and left superolateral crest (B); (5) distance between apex of hiatus and right superolateral crest (A); (6) distance between the superolateral crests (Mustafa et al., 2012)

1.1.7 Other Parameters (Fig 1.6)

1.1.7.1 Vertical Distance from Apex to Dural Sac

The gap between the hiatal tip and the end of dural sac is anatomically significant. This has been measured using detailed imaging techniques, mainly MRI. Normally the dural sac terminates at the level of the lower border of the S1. However, variations in the level of dural sac termination also exist. In 5% males and 8% females the dural sac ended below the S2-S3 disc level. Therefore, the measurement of the length between the hiatal summit and end of dural sac is clinically significant. To determine the proximity the 2^{nd} sacral foramen is used. Average distance between the dural sac and hiatal tip ranges from 5.8-59.96mm. It is advised that during caudal puncture, the epidural needle should not be advanced more than 5mm to avoid dural puncture (Nasr, 2017).

1.1.7.2 Distance from Base to Dural Sac

The caudal end or base of the hiatus is considered a safer approach for access to the "sacral canal" because identification of the apex can prove to be difficult in some cases. The space between the base of the hiatus and the dural sac termination is determined by using MRI. It is measured in the median plane between the midpoint of the hiatal base and 2^{nd} sacral foramen. On average, the distance ranges from 39-85mm (Porzionato, Macchi, Parenti, & De Caro, 2011).

1.1.7.3 Distance at Superolateral Crests

It is the measurement between the right and left superolateral crests on the dorsal surface of the sacrum. This measurement is used as a base to form an inverted triangle. This triangle is used in clinical procedures. The measured mean value is 61.16$\pm$5.42 mm. However racial and individual variations may occur (Singh et al., 2018).

1.1.7.4 Distance from Apex of Hiatus to Superolateral Crests

These are the paired measurements from the superolateral crests till the hiatal apex. Together with the measurements between the superolateral crests they form a triangle. On the right side the recorded mean value is 57.57$\pm$ 10.02mm and on the left side it is 58.32$\pm$10.02 mm (Singh et al., 2018). In 45% of sacra, the triangle is usually equilateral;

however 55% sacra shorter sides have been recorded relative to the base (Aggarwal et al., 2009).

1.2 IDENTIFICATION OF THE HIATUS

Multiple techniques have been tried and tested to identify the hiatus. The blind method employs palpation of the sacral cornua to locate the hiatal area. The hiatal opening is recognized about 5cm (2 inches) above the natal cleft. It has also been observed that the sacral cornua variation also exists. It is a strong influence in identification of the hiatus. A cornual length more than 3mm is necessary for palpation. Cadaveric study has revealed that in some individuals the sacral cornua may be impalpable while in others cornu on one side or both sides may be palpable. In such cases, radiographic imaging facilitates localization (Kao & Lin, 2017). In 46.5% of the Pakistani population, the sacral cornua are bilaterally palpable and in 9% the cornua are flat (Ali et al., 2015).

To accurately localize the hiatus an alternate approach is often utilized. It involves the formation of an inverted triangle at the back of the sacrum. This triangle is usually equilateral; however it may also be isosceles. Its base is formed by a line connecting the superolateral crests (level of the PSIS). On the surface these are recognized by dimples on either side. The limbs of the triangle are formed by lines connecting each superolateral crest to the hiatal apex (Kujur & Gaikwad, 2017). A more accurate method for identification is ultrasonography or fluoroscopy, particularly for "caudal epidural block". Success results from 96.5-100% have been documented with the ultrasound based method (Kim et al., 2014).

1.3 HIATAL CONTENTS AND ITS COVERINGS

The hiatal gap consists of a floor, roof and lateral boundaries. The floor is formed by the anterior wall of the "sacral canal" and the deep posterior sacrococcygeal ligament. The ligament attaches inferiorly to the coccyx and is covered by hyaline cartilage. The hiatus contains the lower sacral and coccygeal nerve roots, filum terminale, fibrous tissue and fatty tissue. The roof of the hiatus is made from interior to exterior by the filum terminale, superficial posterior sacrococcygeal ligament, subcutaneous tissue and skin (Saikia & Sarma, 2016).

Structurally, the posterior sacrococcygeal ligaments are formed by strands of fibrous tissue present in the hiatal opening. The "superficial posterior sacrococcygeal ligament" attaches to the free margins of the hiatal opening and extends downwards to attach to the "coccyx". Fundamentally the "filum terminale" is a continuation of the pia mater covering the "spinal cord". It is made of a delicate strand of fibrous tissue that extends downwards from the end of the "spinal cord (conus medullaris)" to attach to the periosteum of the tailbone. It helps to anchor the spinal cord. As it descends, the "filum terminale" blends with the sacrococcygeal ligament; therefore it is positioned between the deep and superficial parts of the ligament (Standring et al., 2016).

1.4 CLINICAL SIGNIFICANCE OF SACRAL HIATUS

As a portal to access the sacral canal, the sacral hiatus has gained popularity over time. Its distance from the spinal cord enables the clinician to access the epidural space without severe damage to spinal nerves (Singh, 2017). It was initially used in obstetrics for regional block. It is now widely used for sub umbilical surgeries in children as well as adults. An emerging trend is the trans-sacral route to stimulate the sacral spinal nerves for treatment of urinary incontinence, chronic low backache or pelvic pain with steroid inoculations as well as minimally invasive spinal cord surgeries (Saluja et al., 2019).

1.4.1 Epidural anesthesia/analgesia

It is a procedure in which a caudal approach (sacral hiatus) is used to inject an anesthetic agent into the epidural space. It has been utilized for managing chronic back and pelvic pain. Variations of sacral hiatus play an important part in the caudal approach success. In 25% of patients failed procedures are associated with the differences in hiatal anatomy. Parameters of significance in such cases are the apex of the hiatus and its anteroposterior diameter (Chhabra, 2014). Analgesic effect of caudal steroid injections has given pain relief in 71% of individuals experiencing "chronic low back pain". The analgesic effects have lasted for 6 months. The functional assessment has shown improvement 3 months after the caudal injection of steroids. At least a 40% reduction in the disability index has been observed in 81% of patients at 1 week, 6 weeks and 12 weeks after therapy (Shah et al., 2010).

1.4.2 Epiduroscopy

It is a procedure in which the epidural space is explored to identify nerves generating pain in different areas of the body. A catheter with an attached fibreoptic camera is inserted by a small incision at the sacral hiatus. In cases of intractable low back and recurring leg pain, this approach has been predicted to provide a better alternative (Sayhan & Beyaz, 2016).

1.4.3 Thecaloscopy

It is a "minimally invasive procedure" in which the sacral hiatus is used to gain access to the subarachnoid space. It involves a flexible endoscope which enables observation of the thecal space structure and its contents.

The access point for the procedure is selected according to the level of the vertebral column. The sacral hiatus is used for the trans-sacral approach. Among the parameters of the hiatus, the transverse diameter is important for successful and complication-free procedure particularly during endoscope insertion. The lumbosacral angle and the level of dural sac are also significant (Pradhan & Yadav, 2016).

1.4.4 Myelography

It is a form of imaging which is used to examine the subarachnoid space using contrast material under fluoroscopic guidance. The subarachnoid space is accessed through the spinal canal. This procedure is used to visualize the spinal cord, nerve roots, subarachnoid space and spinal column in real-time as the contrast material enters the space. Radiographs can also be obtained simultaneously. It is most commonly used for the detection of pathologies in spinal canal, spinal cord, nerve roots and supplying blood vessels. Images can also assist with surgical planning for spinal instrumentation (McKay et al., 2017). Although the cervical and lumbar approaches are preferred, the trans-sacral route via the sacral hiatus is an alternative (Jones, Shaw, & Jacobson, 1997).

1.4.5 Treatment of Urinary Incontinence

Urinary incontinence is one of the most common complaints postoperatively after prostate surgery especially radical prostatectomy. Symptoms range from leakage with weight lifting to gravitational or continuous dribbling. It is stated to occur due to multiple reasons such as intraoperative damage to the internal sphincter or detrusor denervation leading to poor bladder compliance. Stimulation of the sacral nerves has shown promising results. The sacral foramina and sacral hiatus have been used to stimulate the affected sacrococcygeal nerves. Both access routes have shown relief of symptoms in patients. However the hiatal approach has alleviated symptoms in 60% of patients compared to the foraminal route (ElSawy, Mahran, & Alkushi, 2017).

1.4.6 Surgery for Urological Calculi

The use of sacral hiatus is also implemented in the ureteroscopic treatment of urinary calculi. Beneficial results have been observed in patients given sacral block anesthesia for this procedure. Overall 97.8% of surgeries using this technique for urinary calculi have shown success. Calculi situated in bladder, urethra, distal ureter, and mid-ureter can be successfully removed under sacral block (Zhu et al., 2012).

1.4.7 Prostate Biopsy

A sampling of the prostate is a necessary procedure for the diagnosis of cancer in patients with prostatic hypertrophy and related symptoms. The standard procedure for the biopsy is an ultrasound-guided transrectal approach. This procedure is however painful and uncomfortable for the patient. An anesthetic technique with minimal adverse effects is therefore necessary. The preferred and commonly used method for anesthesia during this procedure is intrarectal local anesthesia accompanied with periprostatic nerve block. However, the pain and discomfort of the patient though reduced is not eliminated. Alternatively, caudal block procedure has shown to effectively decrease the patient pain and discomfort during the biopsy. An added advantage is a block of sacrococcygeal nerves with simultaneous relaxation of the anal sphincter making maneuvering of the ultrasound probe easier in addition to blocking innervation of the perineum and perianal region (Wang, Fu, Ma, Wang, & Gao, 2016).

1.4.8 Pediatric Surgery

In the pediatric group regional anesthesia is most commonly used. It is employed in abdominal as well as lower limb surgeries. Caudal anesthesia is a type of regional anesthesia that is employed either separately or in combination with general anesthesia. It is preferred because of its sparing action of volatile anesthetic agents and neuromuscular blockers with good anesthesia results. Furthermore, levels of adrenocorticotropic hormone, glucose, antidiuretic hormone and beta-endorphin remain normal in the caudal approach. In the blind technique, the patient is position in decubitus position (left) with flexion at the upper and lower hips at 90° and 45° respectively. The angle used for needle insertion is usually 45-60°. After the sacrococcygeal membrane is pierced the needle is advanced 1-3mm into the sacral canal. This distance is considered safe for avoidance of thecal puncture (Abdulayev et al., 2019). In children the success rates of blind technique for identification of sacral hiatus is above 96% (Yang, 2014).

1.4.9 Surgery of Anorectal Disorders

Anorectal disorders are a common issue that affects males and females alike. The prevalence of these disorders is likely to be higher than the number of patients who visit the clinics. Caudal block via the sacral hiatus has been in use for anorectal surgeries since the year 2000. Approach through the sacral canal is favorable for all surgeries in which the sacral and lower lumbar roots innervation are involved. Success rate of 72.2% has been recorded in adults. It has also been observed that with an increase in experience the technique shows better results (Al-sa'adi, 2018). In a similar study, it was observed that 87% of patients found the technique satisfying and would prefer the caudal anesthesia. The numerous advantages stated are: decrease in hospital stay, shorter recovery time, reduced post-operative nursing care and quantity of post-operative analgesics (Malik, Mirani, & Kumar, 2019).

1.4.10 Circumcision

It is the procedure in which the foreskin or prepuce is surgically removed from the tip of the penis. It is a religious obligation, tradition and the most frequently performed surgical procedure worldwide. Ideally it is performed in pediatric patients. Determination of the type of anesthesia to be applied depends upon individual preference, hospital facility, skill of surgeon and anesthetist. Regional anesthesia is preferred to reduce surgical stress and provide ease postoperatively. A variety of analgesic techniques have been used such as dorsal penile block, subcutaneous morphine and caudal block. Comparison between the methods revealed longer period of analgesia with better satisfaction levels from parent and child (Canakci et al., 2017).

1.5 DEVELOPMENT OF SACRAL VERTEBRA

The sacrum originates from 35 ossification centers. Each segment of the sacrum consists of a primary center and 4 secondary centers (Fig 1.4.1). The primary center forms the vertebral body while the secondary centers form the epiphyseal plates and each half of the neural arch. The alae are formed by costal elements of the 1st 3 sacral segments. The lateral parts of the bone including the auricular surface are formed by epiphyseal plates. Like the lumbar vertebra, the 'sacral vertebrae' are initially separated by intervertebral discs at the time of birth. However, by the age of two years the characteristic appearance of the sacrum is seen. By the end of 2 years age the vertebral bodies begin to fuse. At the time of puberty, the costal elements and auricular surfaces also begin fusion. By the age of 22, the lateral epiphyses and costal elements of S3-S4 and S4-S5 are fused. The fusion of S2-S3 follows and segments of S1-S2 during the 4th decade or after that. Little change in morphology has been documented in adult life, however, bilateral asymmetry of the auricular surfaces has been noticed (Veillette, 2011).

1.6 MALFORMATIONS OF SACRUM

Congenital anomalies of the sacrum are heterogeneous. Defects may be minor sacral or coccygeal defects incidentally discovered on radiographic imaging or severely debilitating (Treble, Owen, & Rickwood, 1988). Anomalies related to sacrum include spina bifida. In Pakistan the overall incidence is 34.5%. The prevalence of incomplete spina bifida is 5.5% and a complete defect is 4.5% (Ali et al., 2014). In 12% of the general population, minor defects of the spine are present and seen on radiographs of the chest or lumbar spine (Alexander & Tuan, 2010).

During development, if the posterior elements of the spine fail to fuse a condition called "spina bifida" occurs (Fig 1.4.2). This term generally describes the malformations of the lumbosacral region. Conditions included in this group are "spina bifida cystica" and "spina bifida occulta". "Spina bifida occulta" (SBO) is a disorder in which the posterior elements of the spine do not fuse leaving the neural arch open (Nadeem, 2014). The closure of the vertebral arches is dependent on the induction by the neural tube. With defective development of the neural tube, the vertebral arches also show abnormalities. The two forms of defects are further subdivided according to certain features such as the presence of a hernia sac, contents of the sac and existence or absence of skin coverage.

The “spina bifida cystica” is otherwise known as “spina bifida aperta”. Meningocele, myelomeningocele and myeloschisis are its three clinical forms. The most severe form is myeloschisis, in which the spinal cord is split. The rarest subtype is the meningocele. It is a defect in which the spinal cord is spared, however, meninges are herniated. It is stated that it may be a variant of “spina bifida occulta” as well. If however, a part of the spinal cord is also present in the hernia sac from the spinal canal, then it becomes a myelomeningocele.

Spina bifida occulta is a closed defect in which the lesion is covered by skin. Its subtypes are lipomyelomeningocele and lipomeningocele. In lipomyelomeningocele, the hernia sac contains meninges and neural tissues. The less severe form is the lipomeningocele which according to its name, consists of a hernia sac with adipose tissue and meninges. The most common subtype is ‘spina bifida occulta’ without herniation. Individuals with this defect are usually asymptomatic. This form is discovered on radiographic imaging (Tamas-Csab et al., 2019). The incidence in Pakistan is 28.85% according to studies conducted in Rahim Yar Khan, 19.5% in Karachi, and 28.3% in Peshawar. Around 62.8% of patients presenting with urinary complaints have bony defects of the spine. 13% of these cases had spina bifida occulta (Sadiq, Faiq, & Idrees, 2015).

1.6.1 Sacral Spina Bifida Occulta (SSBO)

A developmental defect in which the laminae of sacral vertebra fail to fuse completely is inferred to be the cause. At the lower end of the vertebral column it is known as “sacral spina bifida occulta” (SSBO). Morphometric studies have revealed that in such cases the posterior wall of the ‘sacral canal’ is absent. In these sacra, the apex of the hiatus cannot be appreciated however; the base can be identified (Gaikwad, Kujur, Jain, Das, & Behera, 2019).

Sacral spina bifida has been graded using dry human sacral vertebrae. The grading system has been established on the number of sacral vertebrae that show a defect in development along the posterior surface of the sacrum. To describe the defect, the level of sacral vertebra and the sacral hiatus have been used as reference points. Four types of defects have been identified (Fig 1.7). They are as follows:

Type I: the defect in the dorsal wall of the sacral canal originates from the top of the S1 spine and continues till the sacral hiatus. The costal elements between S1-S2 and S2-S3 show incomplete fusion resulting in a completely deficient dorsal wall of the sacral canal. The defect is also known as complete spina bifida, 1.4% of sacra have a completely open sacral canal.

Type II: the opening in the dorsal wall of the sacral canal begins at the lower border of S1 and ends at S5. The costal elements are fused, 2.1% of dry sacral bones have this defect.

Type III: the dorsal wall of the sacral canal is deficient from S2 till S5, 22.1% of sacra have this defect.

Type IV: the ventral surface of the sacrum appears normal. The opening in the dorsal wall is from S3 till S5. It has been seen in 33.6% of dry human sacra.

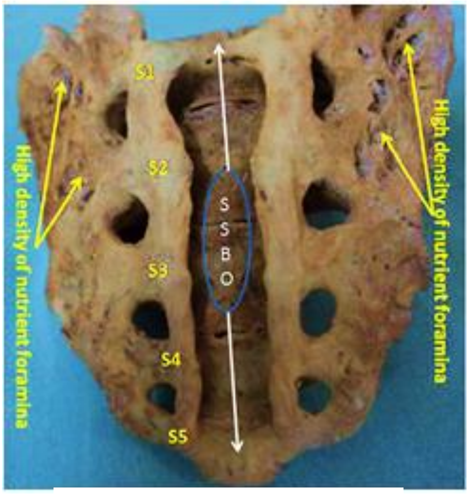
Type V: a small sacral hiatus is present with a length of about 15mm, 1.4% of sacra have this finding (Singh, 2013).

1.6.1.1 Clinical Symptoms of Spina Bifida

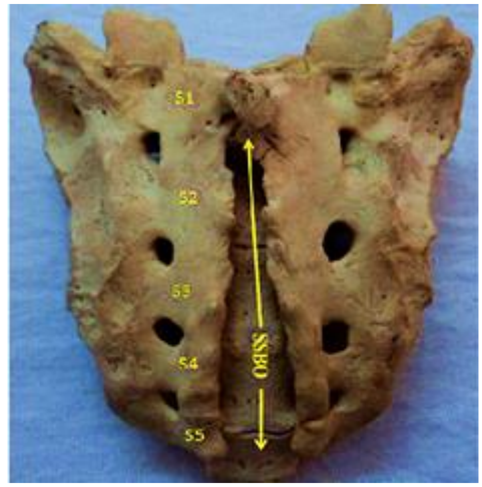
The outcomes of sacral defects are dependent on the number of vertebral segments that are affected. An increase in the neurological and urological effects is directly related to the increase in the number of segments involved. Disorders that are found to be associated with spina bifida include ‘intraspinal lipoma, tethered cord syndrome, genitourinary dysfunction, herniated disc, lumbar spondylolysis, foot deformities, back pain or leg pain’ and syringomyelia (Gregerson, 1997). The majority of individuals with spina bifida occulta are asymptomatic; however, in children functional disorders of the lower urinary tract may be present. Complete spina bifida has been linked with neurologic complaints (Miyazato Sugava, Nishijima, Owan, & Ogawa, 2007).

1.6.2 Transitional Vertebra

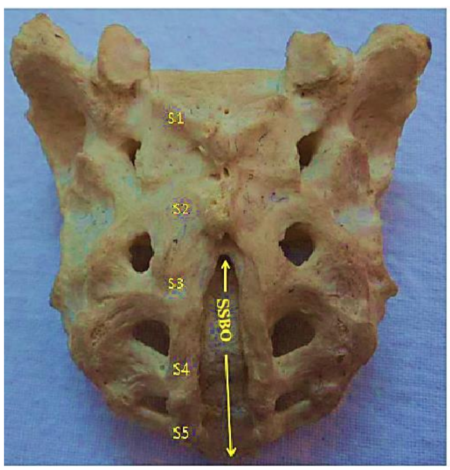
A transitional vertebra is a congenital anomaly of the spine. In this condition a total or partial defect of the ‘transverse process’ of the lowest ‘lumbar’ or ‘sacral vertebra’ is present. The defect may be seen unilaterally or bilaterally. Unilateral defects are present in



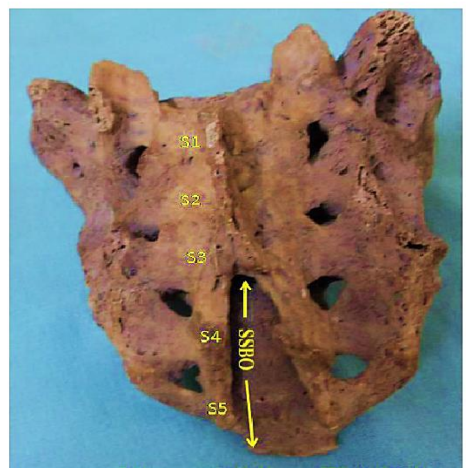
SSBO Type I Defect



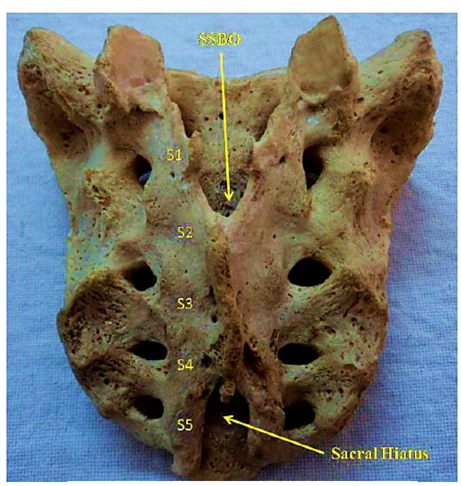
SSBO Type II Defect



SSBO Type III Defect



SSBO Type IV Defect



SSBO Type V Defect

Fig. 1.7 Dry human sacra with sacral spina bifida defect (Singh, 2013)

4% sacra. Bilateral defects are more common and are observed to be prevalent in 36% sacra. Transitional vertebrae have been categorized based on the proximity of the abnormal vertebra towards the lumbar or sacral spine into two types. The two types of transitions that have been documented in the lumbosacral region are lumbarization and sacralization. If a segment of the sacrum is free to act in spinal activity with the lumbar vertebrae it is known as lumbarization. An alternate variation in which a transitional lumbar vertebra becomes a part of the sacrum is identified as sacralization. Transitional vertebrae may be asymptomatic or can cause health problems such as low back pain. It has been observed that both lumbarization and sacralization are associated with back pain (Abbas, Peled, Hershkovitz, & Hamoud, 2019).

1.7 LOW BACK PAIN

Low backache is the 4th most common medical cause of absence from work and increasing disability worldwide. 60-80% of adults experience back pain at some point in their lives. In Pakistan, it is a prominent cause of 'years lived in disability' with an incidence of 37.8% (Vos et al., 2017). According to the chronicity of complaints, low back pain has been regarded as acute, sub-acute and chronic. Acute pain lasts for less than six weeks and more than three months if pain is chronic. Sub-acute back pain lasts between six weeks and three months. "Chronic low back pain" is associated with disability, disruption of daily activities and financial burden.

Low back pain has been classified into categories for clinical diagnosis and treatment purposes. If the pathophysiologic cause of the pain is determined, the backache is categorized a "specific backache". However if the cause is not clear and the pain persists, it is classified as "non-specific backache." It is estimated that around 85% of cases of back pain have an undetermined cause. Various tests carried out to determine the underlying pathology include X-ray, MRI and blood tests. A variety of treatment options are used to treat backache such as analgesic medicines, exercise, and rehabilitation programs. In cases of acute non-specific low back pain, reduction in exercise is preferred to allow healing of the soft tissues. In 15-25% of chronic non-specific back pain cases, physical activity programs containing exercises such as aerobics, muscular strength and flexibility have been observed to decrease pain. 27.3% cases have shown improvements with a decrease in disability following exercise therapy (Gordon & Bloxham, 2016).

Mechanical low back pain has been inferred to be related to anatomical variations of sacral hiatus. It has been stated that in cases of long hiatus where a defect in the dorsal wall of the sacral canal is present, there is a decrease in surface area for the attachment of the extensor muscles of the back, which presents as back pain. In the dry human sacra of low back pain patients the dorsal wall of sacra was deficient in 40% male and 27.2% females. According to the study 7.5% of these cases had no sacral hiatus (Elumalai, Thangamani Sanyal, & Kangarajan, 2016).

1.8 PATHOGENESIS

Pain is a sensation that is mediated by specialized peripheral sensory neurons, the nociceptors. Pain generating stimulus is converted into electrical signals by these receptor and the information is relayed to the brain. Microscopic study reveals that the nociceptor is a pseudo-unipolar neuron. The ‘cell body’ is present in the ‘dorsal root ganglion of the spinal cord’ while the axon is bifurcate. A peripheral branch innervates the skin while the central branch synapses on the neurons in the spinal cord (‘second order neuron’). The pain stimulus is then transmitted to the second order neuron in the dorsal column of the spinal cord then mediated via ascending tracts mesencephalon and thalamus. From the thalamus the information is conveyed to the ‘somatosensory cortex’ of the brain. Majority of the somatosensory information is integrated at the ‘dorsal horn of the spinal cord’. Here multiple interneurons form descending pathways, both inhibitory and facilitatory which modulate transmission of pain generating stimuli. In case of chronic pain, the persistent pain stimulus sensitizes the peripheral and central processes of the nociceptor. Therefore, the excitability of the central nervous system increases. These changes are found in cases of chronic low back pain, osteoarthritis, headache, fibromyalgia and temporomandibular disorders. It has also been stated that delta-A fibers present in joint and muscles could also be involved in this sensitization (Allegri, 2016).

1.9 MODEL OF BACK PAIN

To accurately identify and treat the reasons of lumbago, a comprehensive model of the multiple factors associated with the symptom was created. This model highlights the areas which were previously not considered as important influences in the course of low back pain. This new individualized approach has now been adopted by clinicians worldwide in the treatment of chronic low back pain with focus on improving the quality of life. The term “biopsychosocial” implies that an illness does not occur due to a specific pathophysiology alone, but is related to biological as well as psychosocial factors (Bevers et al., 2016).

1.10 RISK FACTORS

Estimates reveal that in around 5-15% cases of low back pain a cause can be ascertained. In 85-95% of the remaining cases, the cause is unclear (Duthey, 2013). Although regional differences exist in the prevalence and incidence of low back pain, the risk factors are similar. Systematic reviews and cohort studies indicate that the possibility of an episode of low back pain increases in cases with previous history of the complaint and chronic disease conditions. Compared to healthy individuals the odds of low back pain in chronic diseases such as asthma, diabetes, and headache are high (1.6-4.2). Furthermore, it has also been observed that individuals suffering from poor mental health conditions have increased risk of low back pain with odds of 2.52. More specifically, people suffering from depression have high risk of developing low back pain (odds ratio 2.9). Also lifestyle factors such as smoking, obesity and lack of physical activity are associated with incidence of low back pain (Hartvigsen et al., 2018). Supportive evidence in another study has highlighted that advanced age, mental health, level of income, education, and occupation status influence the incidence of low back pain (Hurwitz, Randhawa, Yu, Cote, & Haldeman, 2018). The risk factors are divided into several categories. These are:

1.10.1 Biological

Backache can be derived from various anatomical sources like ‘spinal nerve roots, muscles, fascial structures, bones, joints, intervertebral discs, and abdominal organs’. It can also be neuropathic in origin (Allegri, 2016).

1.10.2 Psychological

Psychosocial factors can also play a significant role in low back pain. It is stated that frequency of pain in lower back is more likely in individuals with negative affectivity, low social support levels at the workplace, high psychological demand, stress, anxiety, depression dissatisfaction with and work low level of job control (Duthey, 2013).

A positive association has been determined between the degree of disability and severity of depression. Analysis of depressed patients with ‘chronic back pain’ has revealed that in depressed individuals, the negative thoughts activate areas of the brain that amplify the pain experienced thereby increasing disability. This perception is because of the increased attention towards the pain sensations, amplifying the pain felt by several degrees (Nassar, Assaf, Farrag, Ibrahim, & Al-Sheekh, 2019). In Pakistan around 55% of patients with low backache experience high levels of anxiety and 48.5% have depression (Sagheer, Khan, & Sharif, 2013).

1.10.3 Body Height and Weight

An association between height and low back pain has been observed suggesting that tall height is a risk factor for the condition. It has been observed that with increase in height, the disk instability potential increases. An association between body mass index and incidence of low back pain has also been observed is multiple studies. A meta-analysis revealed that obese individuals are at high risk of low back pain (Duthey, 2013).

In the Pakistani office workers significant associations of low back pain with body mass index, level of education and physical activity have been observed. The prevalence of low back pain in obese individuals is documented to be 76.9. The prevalence of low back pain is observed to be low in the educated group compared to the low educated group. Furthermore, in the exercising group prevalence of back pain is 21.4% compared to the non-exercising group with 37.1% (Arslan et al., 2016).

1.10.4 Occupational

It is approximated that 37% of cases with lumbago are linked to occupation. Health-care workers, drivers, construction workers are some of the occupations with frequent complaints of back pain. It has been observed that exposure to vibrations, prolonged standing and working postures increase the possibility of pain in lower back. Postures involving 'bending heavily with the trunk', twisting, bending motions of the trunk either simultaneously or separately for prolonged periods predisposes to occupation related low back pain. The repeated twisting and bending increases fatigue of the spinal muscles, reduces recovery time thereby leading to backache (Duthey, 2013).

In Pakistan 32% of healthcare workers suffer from back pain. Amongst those suffering from musculoskeletal problems, 93.1% of the cases were related to working in the same posture for long periods of time and 78.6% from "working in awkward and cramped positions" (Rathore, Attique, & Asma, 2017).

1.11 TREATMENT

The accurate diagnosis of a cause of low back pain can be a challenging process. It has been recommended by guideline that the biopsychosocial model be used for the identification factors related to biological, psychological and social influences. Contrary to common practice, it has been advised to limit the use of laboratory tests and imaging studies in the early management. Tests should be employed in situations such as an infection or other serious conditions. In cases of low back pain, guidelines suggest self-management, physical and psychological therapies along with complementary medicine. Pharmacological and surgical treatments are not recommended in the initial phase of treatment. Currently, active treatments to address psychosocial factors are encouraged. These treatments focus more on the improvement of functioning of the patients. Physical activity in the form of structured exercise in combination with other non-pharmacological options such as acupuncture, massage, spinal manipulation, Tai Chi and yoga are advised. In case of an inadequate response to initial therapy, pharmacologic treatment can be used. NSAIDS are recommended medicines for treatment of pain provided the necessary precautions regarding the side effects are also taken into consideration. Other medicines recommended for short time use include muscle relaxants. In cases of severe radicular pain, epidural injections of local anesthetic and steroids are recommended. Surgery is recommended in patients with severe or progressive neurological deficits and when non-surgical treatments are unsuccessful (Foster et al., 2018).

1.12 HYPOTHESIS

- **Null Hypothesis**

There is no association between different anatomical variations of sacral hiatus and low back pain.

Alternate Hypothesis

There is an association between different anatomical variations of sacral hiatus and low back pain.

1.13 OBJECTIVES OF STUDY

The objectives of the study were to:

- Compare the shape, level of apex, level of base, length, anteroposterior diameter, and transverse width of the sacral hiatus between cases and controls.
- Compare the incidence of variations of sacral hiatus between male and female cases.
- Compare the demographics and patient characteristics between cases and controls.
- Compare the hiatal variations, demographics and patient characteristics within cases
- Determine the relationship of the anatomical variations, demographics and patient characteristics with incidence of low back pain.

1.14 STATEMENT OF THE PROBLEM

Low back pain is ranked amongst the top ten global burden diseases. Non-specific low back pain occurs in the majority of the cases. This study aims to identify the incidence of anatomical variations of sacral hiatus in patients with non-specific low back pain, determine significance of difference between cases and controls, and demographic characteristics. Identification of possible association with anatomical variations of sacral hiatus will help in management of the cases; provide insight for caudal procedures thereby reducing healthcare costs and individual suffering.

1.15 SIGNIFICANCE OF STUDY

The sacral hiatus is commonly used to access the caudal epidural space. Variations of the sacral hiatus are related to decrease in surface area for attachment of extensor muscles at the dorsal surface of the sacrum which causes low back pain without a known cause. Hiatal variations are also attributed to failure of caudal epidural block, caudal steroid injections and their complications. The observations of this study can be used for the education of the general population regarding the lifestyle modifications to prevent non-specific low back pain. It can be useful in the fields of orthopedic surgery, rehabilitation medicine and anesthesia for treatment of chronic pain, subumbilical surgeries, and caudal anesthesia in adults.

1.16 OPERATIONAL DEFINITIONS

1. Acute low back pain: complaints of ache in the area between the ribs and gluteal folds for less than 3 weeks (Hafeez et al., 2013).

2 Chronic low back pain: aching in the area of lower back without relief for more than 3 months (Hafeez et al., 2013).

3. Lifetime prevalence: An event occurring at any point in time of an individual’s life (Hafeez et al., 2013).

4. Low back: “Area on the posterior aspect of the body from lower margin of the twelfth rib to the lower gluteal fold” (Holy et al., 2010).

5. Low back pain: pain in the lower back with or without radiation into one or both lower limbs that lasts for at least one day (Holy et al., 2010).

6. Mechanical Low Back Pain: pain in the back arising from the spine, IV discs, or surrounding soft tissues (Will, Bury, and Miller, 2018).

7. Non-specific low back pain: pain that is not attributable to a recognizable pathology such as infection, cancer, osteoporosis, fracture, structural deformity, inflammation or cauda equina syndrome (Balague, Mannion, Pellise, & Cedraschi, 2012).

8. Point prevalence: An event that occurs at only one moment in a person’s life (Hafeez et al., 2013).

9. Sacral hiatus: a gap on the posterior surface of the sacrum formed by the non-fusion of lamina of S5 or S4 (Sinnatamby et al., 2011).

10. Sub-acute low back pain: ache in the lumbar area that remains from 3 weeks to 3 months (Hafeez et al., 2013).

CHAPTER 2

LITERATURE REVIEW

The sacrum has been the subject of intrigue and research. Study of the sacrum dates back to the ancient civilizations where it was used either as a sacrifice or revered. Its name has been derived from the Greek word "hieron ostoun" meaning "sacred bone". It was also considered necessary for resurrection by the ancient Egyptians. The accurate anatomical description of a five vertebral sacrum was first documented by Leonardo da Vinci. The embryological development was first documented by Bardeen (Nastoulis et al., 2019).

Anthropometric studies have given special attention to an aperture at the lower end on the dorsum of the sacrum; the sacral hiatus. In the clinical practice, it is the site used to access the epidural space (Singh, 2017). The caudal approach has been utilized in pediatric as well as adult populations. Caudal approach during infra-umbilical surgeries has been encouraged due to favorable surgical outcome, achievable anesthetic effects with fewer complications, high levels of patient satisfaction, low costs and reduced hospital stay postoperatively. The procedure has also been performed by the surgeon and with favorable outcomes in association with an increase in the surgeon's experience (Al-sa'adi, 2018). Clinical trials have revealed that variations of the anatomical parameters of the hiatus affect the success rates of caudal procedures. It has been estimated that 25% of caudal epidural failures occur because of variations in hiatal structure (Chandraphilip, Prabavathy, & Jayanthi, 2017).

Development of the sacrum occurs during the embryonic period concomitantly with the formation of the neural tube. Study on mice has revealed that formation of sacrum is induced by the Hox 11 gene. An overexpression of the gene may lead to overgrowth of the sacral lamina and closed or small sacral hiatus. The body and intervertebral discs of the sacrum are developed from sclerotome cells of the paraxial mesoderm. Differentiation of the sclerotome cells is induced by the Pax 1 gene. The neural arches are developed from cells dorsal to the neural tube. It has been observed that these cells express the Pax 9 gene. The expression of this gene controls the growth and fusion of the sacral vertebral lamina. Overexpression has been linked to the increased cellular proliferation of chondrocytes and osteocytes and associated fusion of vertebral laminae below the fourth sacral spine as well as formation of tubercles seen on either side of a small sacral hiatus (Singh, 2018).

Morphometric and morphological studies of the hiatus have described its structure relative to qualitative and quantitative parameters. Descriptive characteristics such as the shape, level of apex and level of the base have been observed on gross appearance alone. To ascertain the dimensions of the hiatus its length, width, and anteroposterior diameter have been measured using specialized tools. Because the sacral hiatus is located beneath the skin and fat, clinicians have developed different techniques for its identification. Most commonly used method is palpation of the area 2 inches above the natal cleft to identify the hiatal apex as well as the posterior superior iliac spines. Once identified measurements between the bony structures on the dorsal surface of the sacrum are recorded (Thirumagal, Babu, & Mohanraj, 2018). The parameters consist of those that are used to identify the hiatal apex such as the distances between the superolateral crests, hiatal apex and each of the superolateral crests. These crests are superimposed by the posterior superior iliac spines which are used alternatively. The measurements form an inverted triangle that directs towards the sacral hiatus. The arms of the triangle are formed by the values between the right and left superolateral crest and the apex of the sacral hiatus, while the base is the distance between the two crests. Another measurement is helpful in determining the length of the epidural needle for caudal procedure such as the distance between the hiatal apex and second sacral foramen or spine. To determine a safe entry point the distance between hiatal base and the second sacral foramen is also measured (Saha, Bhattacharya, Uzzamah, Mazumdar, & Mazumdar, 2016). In most cases this triangle is equilateral however with variations in the measurements the triangle may even be isosceles. This variation has been observed in fetuses and younger children until the age of 10 years. In adults an equilateral triangle has been observed. It has been inferred that variation in triangle shape is due to incomplete growth of the vertebrae in younger age groups (Abukawa et al., 2015).

Identification of the hiatus has also been a subject of radiographic studies, especially in the pediatric population because the caudal approach has been commonly employed during surgeries. In adults, several variations have also been detected. It has been estimated that around 4% do not have a sacral hiatus and sacral cornua are deficient in around 53% of cases. Failure rates of caudal procedures because of difficulty in palpation of the hiatus and its variations have led to the adaptation and innovation of alternatives. The use of ultrasound guidance for hiatal identification has shown promising results. Ultrasound use for caudal procedures has enabled accurate identification of the hiatus with direct visualization of the caudal space. It has also been used to determine the anteroposterior diameter of the epidural space and its expansion during injection of local anesthetic agent (Abukawa et al., 2015). Using the ultrasound technique, an optimal angle for needle insertion has also been estimated in adults. The ideal angle for needle insertion in caudal epidural steroid injection in the Iranian population is 71.04° (Gökçek & Kaydu, 2018).

Cadaveric study has revealed that identification of the hiatus by the palpatory method or blind technique is dependent on the length of the sacral cornua. The sacral cornua are defined as the projections formed by the vestigial remnants of the inferior articular processes of the 5^{th} sacral vertebra (Trinh, Hashmi, & Massoud, 2020). The palpability of the cornua is dependent upon the bilateral length. The cornua may be palpable bilaterally, unilaterally or flat (impalpable). A cornual length of 3mm or more has been deemed necessary for successful palpation. In addition to the cornual length, the body mass index and the distance of the cornua from the skin also influences their identification. It has been observed that in obese individuals, palpation of the cornua has not been possible (Nakahashi et al., 2019). In the Pakistani individuals the sacral cornua have been bilaterally palpable in 46.5% and impalpable in 9% (Ali et al., 2015). In the pediatric population hiatal identification using ultrasound guidance has yielded 95% success rate on the first try. In comparison the landmark technique that showed positive results in 70.83% cases (Riaz, Shah, & Jafri, 2019).

Based on its appearance the sacral hiatus has been commonly described as a triangular opening however other shapes of the hiatus have also been reported. The variations of hiatal shape have been documented within the same population, gender as well as race. The most prevalent shapes observed have been the inverted U and V. Variants such as the dumbbell, bifid, irregular, and M shapes have been less frequently observed. These variants are attributed to the different growth patterns of the bony prominences on either side of the hiatus. The inverted U shape (70.09%) has been observed in West Bengal (Saha et al., 2016) as well as Indian populations (38.5%) (Pundge et al., 2017). On the contrary, studies conducted in the African population detected the inverted V shape in higher frequency

(32.1%). Although no significant association between shape and gender has been established; the inverted U shape has been observed commonly in female sacra whereas the inverted V shape has been seen in male sacra. Furthermore clinical trials have suggested that the inverted U and V shapes may allow easy access to the sacral canal in blind technique compared to the other variants in which the bony prominences may hinder needle advancement (Njihia, Awori, & Gikenye, 2011). An analysis of variance has detected significant variations in hiatal length in association with its shape (p=0.003) (Ukoha et al., 2014).

The 'apex of the sacral hiatus' is the highest point located inferior to the median sacral crest. It has been generally identified at the level of the 4th sacral vertebra. It is the site that has been used for insertion of an epidural needle or equipment to reach the epidural space. Recorded variations in the location of the apex level include the 3rd less commonly 5th, 2nd and rarely 1st sacral vertebra. These alterations are stated to significantly increase the chances of complications such as dural or vascular puncture during trans-sacral procedures (Thirumagal et al., 2018). In the Indian and African populations the apex of the hiatus has been commonly observed at level of 4th sacral vertebra. Regional variations of prevalence have been documented in the Indian sacra such as 80% prevalence in southern (Chandraphilip et al., 2017) and 66% in the western regions (Malwalkar & Bhosale, 2016). In the African population, the prevalence of 62% has been observed (Njihia et al., 2011). It has also been noticed that significant variations in length and transverse width of the hiatus occur in relation to the level of its apex (Ukoha et al., 2014). Studies have also been conducted to determine the hiatal variations in 'low back pain' cases. In male (47.14%) and female (46.39%) patients the apex was predominantly observed at the level of third sacral vertebra (Bhadra & Saha, 2017).

The base is the part located at the lower end of the hiatal opening between the sacral cornua. The level of base of the hiatus is one of the non-metric parameters. It has been observed most commonly at the level of the fifth sacral vertebra. It has also been sighted at the level of the fourth or third sacral vertebra and the coccyx. It is regarded as a safer area to access the caudal epidural space compared to the apex (Senthamizhselvi, Latha, Sivaranjani, Karthikeyan, & Siva, 2017). In the southern regions of India the base has been observed at level of fifth sacral vertebra in 90% of sacra (Chandraphilip et al., 2017). No significant variations in length, width and transverse diameter of the hiatus have been observed with changes in the level of its base (Ukoha et al., 2014).

Vertically the hiatus ranges from the termination of the sacral canal till the intercornual space. A long or short hiatus may present as a challenge when administering caudal analgesia or anesthesia. The hiatal length reportedly has a significant influence on the structure of the hiatus and its contents. It is dependent upon the level of union of the sacral vertebral laminae. A long hiatus has been observed in sacra with non-union of lamina of the third or second sacral vertebrae. In such cases a high lying apex has also been observed. A long hiatus has also been associated with malformations such as spina bifida occulta, urinary incontinence, low backache and an increased incidence of iatrogenic dural puncture (Kumari, Kumari, Prasad, Britto, & Subratanag, 2016). Furthermore variations in the length of the hiatus have been seen with variations of its shapes. The recorded values of length in relation to the shape of the hiatus is: 22.17 ± 8.42mm (inverted U), 20.91 ± 9.88mm (inverted V), 13.50 ± 1.08 mm (dumbbell), 11.03 ± 2.48 mm (bifid), and 8.20 ± 2.51mm (irregular). The analysis of variance has revealed a significant difference in the length of the hiatus in relation to its shape and level of apex (Ukoha et al., 2014). It has been determined that the length of the hiatus plays a significant role in prediction of successful access to the sacral canal. It has been concluded that hiatal lengths less than 17.6mm may be associated with difficulty or failure of the caudal procedures. This has been attributed to the decrease in length of the sacrococcygeal ligament and its ossification with advancing age (Kim et al., 2014).

The hiatal width is the diameter of the hiatus measured from the tip of one sacral cornu to the other in a transverse plane. Therefore it has been alternatively called the intercornual distance or transverse diameter (Vedapriya et al., 2013). This measurement has been used to determine the feasibility of interventional procedures such as epiduroscopy, fluoroscopy, myelography and laminectomy. In these interventions, specialized equipment is inserted into the caudal epidural space via the sacral hiatus. Usually, the hiatus has been reported to be wide enough for such procedures; however, in cases of overgrowth of bony projections around it, problems have been known to occur. It has been advised that equipment to be used for caudal access should be circular in shape, flat and flexible (Bodmer et al., 2017). The average measured width of the hiatus is 14.9 mm (males and females) (Trinh et al., 2020). Values of the width have also been observed to vary with the shape of the hiatus. Width measurements according to the shape of the hiatus are: 12.45 ± 2.80 mm (inverted U); 12.81 ± 3.52 mm (inverted V); 13.50 ± 1.08mm (dumbbell); 11.03 ± 2.48mm (bifid), and 8.20 ± 2.51mm (irregular). The recorded values revealed significant variation in the transverse width in relation to the shape and level of apex of the hiatus (Ukoha et al., 2014). The anteroposterior diameter of the hiatus is the measured distance of midsagittal section of the sacral canal. It is the depth of the hiatus at its apex. It has a significant role in trans-sacral route of needle insertion. It has been reported that the depth may vary from less than 2 mm to greater than 10 mm (1 cm). The depth of the hiatus helps clinicians to determine the size (gauge) of the needle to be used. It is reported that in hiatuses with depth of less than 3 mm, needles no larger than 21-gauge can be utilized. In 5% of the adult population, a depth of less than 3 mm has been recorded (Winnie, 2016). In the Indian sacra hiatal depth is 6.0 mm (Chandraphilip et al., 2017) similar to observations made in the African population where it is 6.4mm (Nijihia et al., 2011). Variations in the depth have also been observed in relation to the hiatal shape. The values observed according to the shape revealed anteroposterior diameters of 5.26 ± 1.83 mm (inverted U), 6.07 ± 2.06 mm (inverted V), 4.78 ± 0.52mm (dumbbell), 4.60 ± 1.73mm (bifid) and 5.80 ± 1.70 mm (irregular). No significant relation was found between the anteroposterior diameter and shape of the hiatus (Ukoha et al., 2014). It has also been detected that the anteroposterior diameter is significantly related to incidence of caudal epidural failure. Depth of less than 3.7mm is predictive of difficult access to the sacral canal (Kim et al., 2014).

In addition to the measurements related to the morphometry of the sacral hiatus, other parameters such as an optimal angle for needle insertion, safe distance for needle advancement and distance from the hiatus to the termination of the dural sac have also been recorded. The vertebral canal at the sacral region begins at the 1st sacral vertebra and ends at the sacral hiatus (Aggarwal et al., 2009). The part of the epidural space that is present below the second sacral vertebra level is defined as the caudal epidural space (Saker et al., 2017). Surgical anatomy of the epidural space based on MRI images and cadaveric dissection has revealed that the dural sac normally ends at the level of the upper or lower border of the second sacral vertebra. This finding has been observed in more than 80% individuals (Pokanan, Borsu, & Hansasusta, 2019; Trinh et al., 2020). In dry human sacra the level of dural sac termination corresponds to the second sacral foramen or spine on the dorsal surface. Therefore the level of the second sacral foramen has been used as a landmark to record the proximities of the hiatal apex and base to the dural sac. A significant association between the level of dural sac termination and level of hiatal apex has been observed in sacra with an apex above the level of third sacral vertebra. Observations of these cases revealed an increase in the incidence of dural puncture. It has also been noticed that variations in the level of dural sac termination are significantly related to age (Trinh et al., 2020).

Anatomically, the structure of the caudal epidural canal in children differs from that seen in adults. Observations of the sacrum during the early post-natal period have revealed that although the sacral vertebrae are five in number, the vertebrae are not fused, resembling the lumbar region. The complete fusion of the sacrum is seen between the ages of 25 and 30 years. Therefore, the dorsal wall of the sacral canal is open above the third or fourth sacral vertebra (apex of the hiatus). This reduces the distance between an epidural need and the termination of the dural sac in children. The recorded length of the sacrococcygeal ligament in children is also shorter compared to adults (Kim, Park, & Lee, 2016). The distance between the dural sac and apex of the hiatus is 3-13cm (30-130mm) in children (Aggarwal, Sahni, Kaur, Batra, & Sondekoppam, 2012) whereas in adults the recorded distance ranges from 34-80 mm. Therefore in the pediatric group a smaller angle of needle insertion has been advised (21°) (Porzionato et al., 2011).

Critical analyses of the hiatal anatomy have been conducted through virtual autopsy and anthropometric study of dry human sacra as well as observation in situ with latest technology such as CT, MRI, digital radiographs, and ultrasound. Amongst these methods, dry human sacra have been employed most frequently for morphometric and morphological analysis of the hiatal parameters. To study the surgical anatomy of the hiatus, radiographic images of the lumbosacral spine have been used. These have enabled the determination the hiatal apex, base, length and width as well as anteroposterior diameter in vivo (Porzionato et al., 2011). On the other hand CT, MRI and ultrasound based images have been used to measure the dimensions of the sacral hiatus as well its relative proximity to the contents of the sacral canal (Kim et al., 2014).

Regional anesthesia has been used frequently during surgical procedures. The caudal approach has been gaining popularity in minor anorectal surgery although it was avoided due to apprehension of per-operative and post-operative pain. It has been observed that more than 80% of surgeries have been performed successfully using this method. Surgical procedures such as hemorrhoidectomy, drainage of perianal abscess, lateral sphincterotomy, and fistulectomy have been successfully performed under caudal block. The caudal block procedure involves the injection of anesthetic agent into the epidural space by perforating the sacrococcygeal ligament covering sacral hiatus. Data analysis has revealed that in 79% of surgeries, the anesthesia was adequate and successful. Patient responses to caudal anesthesia revealed approval of method in 87%, satisfaction in per-operative analgesia in 88.88%, and selection of caudal block for surgery in 87% patients (Shah & Choudhary, 2007).

The herniation of the intervertebral disc at the lumbar spine has been known to be one of the causes associated with debilitating pain. Affected individuals have been documented to experience backache, leg pain, numbness or weakness of the leg, painful foot drop, dysfunctional bladder, or cauda equina syndrome. The condition has been managed conservatively however in severe cases surgical treatment becomes imperative. Amongst the options that have been performed, an emerging trend in the minimally invasive lumbar discectomy has been documented. This endoscopic method has been performed via the sacral hiatus under fluoroscopic guidance. The method has showed promising results although complications have also been reported. To compare the relief of symptoms in the operated cases, the visual analogue scale for pain has been used in which the pain is scored on degree of severity from minimum to maximum (1 to 10). A case series assessing the success rate of the minimally invasive surgical technique reported significant reduction in the visual analogue scale scores for leg pain (7.1 to 2.6) at baseline as well as back pain (5.9 to 2.7) after three months (NICE guidelines, 2016).

Neuromodulation of the sacral nerves for the treatment of ‘chronic pelvic pain’ is another emerging use of the sacral hiatus. Pelvic pain is termed chronic when it lasts for minimum six months without surgical etiology. Annually it affects 38.3 out of every 1000 individuals in the UK and around 9 million women in the United States. Pelvic pain has been related to musculoskeletal, neurovascular and visceral mechanisms. Several triggers of the pain have been identified such as endometriosis, infection, assault or other injuries, and trauma during childbirth (Vancaillie, Kite, Howard, & Chow, 2018). To treat the pain the afferent roots of the third sacral nerves are usually stimulated. The stimulation helps to restore the balance between the reflexes for inhibition and excitation, giving back control to the brainstem. The observed range of pain relief assessed by the visual analogue scale lies between 35 and 52%. Two approaches have been documented, each with significant results in pain reduction; anterograde and retrograde. In the former approach, the sacral hiatus is punctured and the electrical stimulation device that is inserted is advanced in the cranial direction. In the latter method, lumbar puncture is used to access the epidural space and the electrode is advanced in the caudal direction. Review of data has revealed that both approaches provide equally significant pain relief and that the caudal approach is preferred (Mahran et al., 2019).

Sacral neuromodulation is a non-invasive method that has been approved by the FDA of the US as a treatment option for lower urinary tract dysfunction. The procedure can be performed under general or local anesthesia. Sacral neuromodulation has been used for treatment of urinary complaints such as incontinence, urgency and frequency. It has also been used for the relief of symptoms of interstitial cystitis, urinary retention, without obstruction, urinary urge and fecal incontinence. It involves stimulation of sacral nerve roots externally by implantation of electrodes into the epidural space. Amongst the different approaches, implantation of electrode(s) via the sacral hiatus route provided safe and significant results. Temporary and permanent implantation device options are available depending on the preference and improvement of individual condition. Studies evaluating permanent implantation have revealed successful results ranging from 66% to 77% (Sokal, Zieliński, & Harat, 2015).

The use of sacral hiatus for caudal anesthesia has also been reported in an adult patient with Duchene muscular dystrophy. This is a genetic disorder carried on the X chromosome with high prevalence compared to others. Patients suffering from this condition exhibit neuromuscular weakness, skeletal deformities and eventually cardiac or respiratory failure culminating in death. Surgical procedures in these patients present a challenge for the anesthetist because of disease effects on the cardiopulmonary system. Therefore, alternative techniques for anesthesia are being explored. A case report documented successful debridement of an ischial pressure sore in an adult patient with Duchene muscular dystrophy. The patient had history of restrictive lung disease with chronic respiratory failure, dysphagia and swallowing dysfunction. Regional anesthesia via the sacral hiatus was offered to the patient because of the altered anatomy of the lumbar spine. For identification of the hiatus ultrasound guidance was used. The surgeons reported minimal intraoperative blood loss, no negative effects on the heart rate and blood pressure of the patient. Uneventful postoperative recovery and timely discharge were also recorded (Shafy et al., 2018).

The caudal approach has also been used in adjunct to spinal anesthesia in infants with congenital heart defects as well as poor response to general anesthesia. Because the spinal anesthesia alone provides the surgeons with a one hour operative period, its combination with caudal approach has been used to increase the anesthesia duration. This has enabled successful surgery without risk of neurocognitive effects which have been associated with general anesthesia. Therefore it has been considered as a feasible alternative (Geyer et al., 2018). Furthermore, it has also been reported that in patients administered anesthesia via the sacral hiatus, there has been a marked reduction in the stress response. This has been attributed to the suppression of neurohormonal factors responsible for producing the stress response (Seyedhejazi, 2008).

An emerging trend is also reported in the use of caudal approach for pain relief in gastroschisis surgical repair. Gastroschisis is defined as the abdominal defect produced due to the incomplete closure of the anterior abdominal wall during embryonic development. It is characterized by protrusion of the abdominal contents in a sac outside of the abdominal cavity. Surgery is used to repair the defect and return the displaced contents to the abdominal cavity. Usually the general anesthesia approach is used for the surgery, however reports of apnea post-operatively with the need for mechanical ventilation has led to the use of the caudal approach. This approach has been preferred over spinal anesthesia by the surgeons because of the complications associated with it such as difficulty in accurate determination of the spinal level and increase chances of complications after return of abdominal contents. A collection of case reports has recorded successful surgical outcomes in gastrochisis surgeries that have been performed under caudal anesthesia particularly in pre-mature infants. The method has been encouraged for future use in abdominal surgeries for the pre-mature infants and developing countries with limitation of resources (Kasat, Dave, Shah, & Mahajan, 2017).

Epidural steroid injection has become a commonly used method. This route directly delivers medicine into the epidural space and relieves pain in instances such as degeneration of spine, stenosis of central canal and neuronal foramina (Shim et al., 2017). Another condition in which this technique has proved to be beneficial is sciatica. It is the 'unilateral, well-localized leg pain that approximates to the dermatomal distribution of the sciatic nerve and normally radiates to the foot or toes.' Associated symptoms include paresthesia and numbness. Treatment of this condition with the use of steroid injections has become common practice. Steroids help to reduce the inflammation and inhibit the ectopic discharges from injured nerves. Investigation of efficacy of steroid injections via the caudal route has revealed promising results in 57.1% patients. Improvement in the disability and pain score have been documented in patients receiving an epidural steroid injection. It has also provided pain relief to the patient allowing them time for further improvement with physiotherapy (Shah et al., 2011).

Widespread use of the sacral hiatus for administration of regional anesthesia in various general and special surgical practices has been documented. In the past it was employed in the obstetric practice during the second stage of labor. However its use in conditions such as: post-herpetic neuralgia, diabetic polyneuropathy, complex regional pain syndromes, orchalgia, prognostic neural blockade and sympathetic block is also documented (Winnie, 2016).

Study of the structural morphology of the sacral hiatus has additionally described that hiatal variations are associated with symptoms of low back pain. Comparison of parameters between normal individuals and patients of low back pain was conducted. The findings of shape that were recorded are 39% cases had inverted U, 30% inverted V, 21% irregular, 3% dumbbell, and 2% bifid. No sacral hiatus was found in 2% of cases. In 2% cases the opening of the hiatus was obliterated by bony overgrowth, 3% had deficient dorsal sacral wall, 34% had apex at S2, 52% at S3, and in 9% at S4. The base was observed at S4 in 53%, S5 in 32% and S3 in 10% cases. In 5% of the cases, the base could not be ascertained because of defect in dorsal sacral wall and bony overgrowth. The length ranged from 12mm-51mm in low back pain cases. The intercornual distance ranged from minimum

14mm to maximum 32mm. Minimum recorded depth was 3.7mm and maximum depth was 15mm in the cases (Elumalai et al., 2016). It has been concluded that the variations can be responsible for reduced surface area for muscle attachment and its resulting pain complaints upon exertion (Elumalai et al., 2016; Kumar et al., 2009; Vasuki et al., 2016).

'Low back' is described as the area of the back extending from the lower margin of the 12th ribs to the inferior gluteal fold. Lumbago is the pain in the lower back that may or may not radiate into the limb(s) and persists for at least a day. Globally low back pain is the 4th leading cause of disability-adjusted life years. Point prevalence worldwide is 9.4% (Grabovac & Dormer, 2019). In the Pakistani population it is the second most important cause of "years lived in disability" (Hurwitz et al, 2018). Overall occurrence of back pain and 'chronic back pain' is 35.1% and 6.1% respectively. Country based analysis reported prevalence of 13.7% in China and 57.1% in Nepal. In Bangladesh and Brazil recorded prevalence rates are high 53.1% and 52.0% respectively. Myanmar has the lowest prevalence for 'chronic back pain' (0.6%). The highest prevalence of chronic back pain was observed in Morocco (16.5%) and Nepal (16.4%) (Stubbs et al., 2016).

Description of low back pain has been used to further divide the cases according to the duration of symptoms for diagnosis and appropriate treatment. Pain is categorized as acute if it persists for minimum three weeks; subacute pain ranges from three weeks to three months and chronic pain extends beyond three months (Hafeez et al., 2013). Pain without a known patho-anatomical cause is termed non-specific whereas the opposite applies to specific pain. The WHO has stated that around 70% of the population of industrialized countries suffers from 'non-specific low back pain'. People between the ages of 35 and 55 years have been more affected. Epidemiological studies have also detected a rising prevalence of low back pain in younger age groups and both genders. A national survey conducted in Austria revealed 25% point prevalence and one-year prevalence of around 10% in respondents (Grabovac and Dormer, 2019).

Low back pain has been associated with a broad range of factors. The activities associated with development of low back pain have been divided into work related, physical, psychological, and activities of daily living (Hurwitz et al., 2018). Work related factors include nature of job and working hours. Physical factors include age, gender, and level of physical activity. Psychological factors are those related to individual mental health such as depression (El-Metwally et al., 2019), anxiety, and stress (Khan, Moin Uddin, Chowdhury, & Guha, 2014).

Work related factors such as heavy weight lifting, excessive bending, twisting, and vibrations have been commonly observed in low back pain patients. It is estimated that 30.9% of disability is associated with occupational related factors (Hurwitz et al., 2018). A high prevalence has been observed amongst healthcare workers. One-year point prevalence in this group has been recorded between 45% and 77% (Karahan, Kav, Abbasoglu, & Dogan, 2009). A significant association has been reported between severity ($p=0.010$) and frequency ($p< 0.001$) of low back pain with occupation (Su et al., 2018). A high prevalence of low back pain has also been observed in Pakistani medical students with mild to moderate levels of disability (Shirazi et al., 2017). Low back pain prevalence of 72.8% was also reported amongst Pakistani female nurses working seven to eight hours on a daily basis. Analysis of variance revealed significant association between the duration of occupation ($p=0.017$) and occurrence of low back pain. Significant association was also detected between intensity of low back pain and duration of working hours ($p= 0.048$) (Khan, Tanveer, Ahmad, & Gilani, 2019). Furthermore, prevalence amongst different occupational groups has revealed prevalence values of: 30.1% in housewives, 18.1% in office workers and 14.7% in private jobs (truck drivers and shopkeepers) (Zafar et al., 2018).

The effects of BMI on low back pain have also been noted. A high BMI has been reported to cause 5.5% of years lived with disability due to low back pain (Hurwitz et al., 2018). The WHO has divided the BMI into five categories which are: normal weight (18.5-24.9), overweight (25-29.9), obese (30-34.9), obese class I or severely obese (35-39.9) and obese class II or morbidly obese (>40). Reported prevalence of low back pain is highest in morbidly obese (72.8%) and lowest in normal or underweight individuals (47.5%). Comparison between the values revealed a statistically higher prevalence in obese patients ($p\leq0.0001$). A significant association has been reported between BMI values above 25 and the prevalence of low back pain (O.R=1.35; $p=0.021$) (Su et al., 2018).

Investigation of an association between daily activities with low back pain revealed a strong relationship (O.R=2.01). Walking and bending have been regarded as basic activities of daily living. More complex activities such as cooking, bathing and getting dressed were categorized as instrumental activities for daily living. A strong association was also found between these and low back pain (O.R= 2.17). A cohort study conducted in Thailand assessing people of the age groups from 30 till 60 years revealed that 30% reported low back pain. Amongst these 6% experienced difficulty in bending, 3% experience problems in walking, 2.2% were unable to climb stairs and 2.9% had difficulty getting dressed (Grabovac and Dormer, 2019). In the Pakistani population 41.6% of low back pain cases were due to bending or twisting body movements, 76.3% had lack of physical exercise, 50.4% with prolonged sitting and 48.5% after lifting heavy weights (Zafar et al., 2018).

Depression is reportedly the leading cause of mental health related morbidity globally. Around 10-44% individuals are affected by it in developing countries. In Pakistan the prevalence of depression and anxiety ranges between 22% and 60% (Ahmed, Enaam, Iqbal, Murtaza, & Bashir, 2016). A significant association between prevalence (O.R=1.38, p=0.048), severity (O.R=2.21, $p \leq 0.001$) and frequency (O.R=1.92, $p \leq 0.001$) of low back pain has been reported with depression (Su, Kusin, Li, Ahm, & Ahm, 2018). In the Pakistani population 28.8% patients of low back pain had depression (Zafar et al., 2018).

Advancing age is another risk factor for low back pain. Studies have revealed that degeneration of the intervertebral disc and spine that occurs with increasing age also increases the prevalence of low back pain (Khan et al, 2014). Prevalence of chronic back pain in 18 to 29 years is 24.6% compared to the 70 to 79 years age group with 47.1% (Husky, Farin, Compagnone, Fermanian, & Kovess-Masfety, 2018). Odds ratio of 1.03 has been reported. It was inferred that with an increase in age by one year, the odds of low back pain increase by three times (Biglarian et al., 2012).

Although low back pain is known to affect males and females, variation in prevalence exists. A higher prevalence has been observed in females (41.3%) as compared to males (34.3%) (Husky et al., 2018). An analysis of 98 different studies compared the median prevalence ratio of low back pain in females and males belonging to different age groups. The study found prevalence ratio of 1.310 in ages 6-19 years, 1.140 in 20-50 years age group, and 1.270 in ages 50 and above. Findings suggested a higher prevalence of low back pain in females of all age groups (Wang, Wang, & Kaplar, 2016). Furthermore it has also been found that severity of low back pain is significantly associated with female gender (O.R= 1.36, p =0.023) (Su et al., 2018).

Assessment of the different factors associated with low back pain has revealed a significant relationship with education. It has been observed that with increase in education level, there is decrease in the prevalence of low back pain. It has been reported that education acts as a protective factor against the condition (Husky et al., 2018). Similar findings were found in the Pakistani population ($p=0.002$) (Arslan et al., 2016). Supportive data has also been found in the Iranian population where statistically significant difference in prevalence of low back pain has been reported with education level. In the study education levels were divided on the basis of years of education into three categorical groups: basic (0-8years), moderate (9-12 years) and high (>12 years) level. Highest prevalence of low back pain was observed in the basic education group (33.9%) as compared to moderate (20.2%) and high (15.0%) levels (Biglarian et al., 2012).

Marital status has also been assessed for association with low back pain. Higher point prevalence of low back pain has been reported in married individuals. A significant association has been observed between marital status and lifetime prevalence of low back pain ($p \leq 0.001$) among the Pakistani population (Arslan et al., 2016). Similar results have been found in the French population. They reported higher prevalence of low back pain in adults who were in a relationship (39.2%) as compared to those who were single (36.9%) (Husky et al., 2018). In the Iranian population prevalence in the married group (31.2%) was also higher than in the unmarried group (19.1%). The findings detected a significant association between marital status and risk of low back pain (O.R=1.51, $p \leq 0.001$) (Biglarian et al., 2012).

The risk of low back pain is also related to personal habits. According to the Iranian National Survey, the risk of low back pain increases with duration of smoking (O.R: 1.40). This could be explained by the decreased absorption of calcium caused by nicotine in the cigarettes (Biglarian et al., 2012). In the Pakistani people suffering from low back pain 16.5% are smokers. Previous studies also state that smoking is related with higher incidence and prevalence of low back pain (Zafar et al., 2018). A significant association between the two variables has been detected (O.R= 1.87, $p \leq 0.001$) (Su et al., 2018).

Exercise has many benefits for non-specific low back pain cases such as reduction in stress level, increased muscular strength, improved blood circulation with tissue repair as well as healing and improvement in mobility (Gordon & Bloxham, 2016). A study among office workers with low back pain in Pakistan observed a point prevalence of 37.1% in the sedentary and 21.4% in the exercising individuals (Arslan et al., 2016). Recent studies have reported that around 76.3% of patients suffering from chronic low back pain have no physical activity in their regular routines (Zafar et al., 2018).

Symptom of lumbago also has an association with congenital malformations of the spine such as lumbo-sacral transitional vertebrae and spina bifida. In the general population 4%-30% people lumbosacral transitional vertebrae have been reported as an incidental finding. Transitional vertebrae are changes in morphology of the spine in which lumbarization of the 1st sacral vertebra or sacralization of 5th lumbar vertebra may occur. The anomaly may be present unilaterally or bilaterally. A case in which the vertebral anomaly causes back pain is referred to as “Bertolotti Syndrome”. The pain may occur due to compression of a spinal nerve, the articulation itself, overgrowth of a contralateral facet, and instability or premature degeneration of the vertebra (Konin and Walz, 2010; Kundi et al., 2016).

Clinically low back pain is assessed according to criteria related to its severity, related functional disability, and its emotional burden. Two categories of tools are used for establishment of its diagnosis and planning of appropriate management. These are categorized into those that are applicable to pain in general (generic) and condition-specific tools. The tools may be used independently or in combination. To ensure thorough pain assessment the condition-specific tools are often combined with a health-related quality of life tool (HRQoL). Review of data has described that nine major tools have been used for pain assessment. The most commonly used tools are the Roland Morris Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI), and Quebec Back Pain Disability Scale (QBPDS) (Garg, Pathak, Churyukanov, Uppin, & Solobodin, 2020).

RMDQ is a multidimensional questionnaire that is designed to evaluate self-rated physical disability caused by low back pain. Different formats of the questionnaire are available such as 24, 18 and 11 item. It enables the clinician to follow changes in the patient in a day to day basis. The questions address factors related to low back pain such as psychosocial (6 questions), sleep or rest (2 questions), physical functioning (15 questions), eating (1 question), home management (2 questions), and frequency of back pain (1 question). The score of the questionnaire is determined by the sum of the number of boxes ticked. Minimum score is 0 (no disability) to maximum scores of 11, 18 and 24 (maximum disability) according to the total number of questions. It is one of the most commonly used questionnaires in the clinical setting. It can also be used for diagnosis of prolapsed intervertebral disc, spondylosis, spondylolisthesis and infections of the spine (Garg et al., 2020)

ODI is a patient completed questionnaire specified for low back pain in adults with no cognitive impairment. It comprises of 10 questions that are related to the intensity of pain, effect of pain on sex life, social life and travelling. A subjective percentage score of the disability related to performance of everyday life tasks is determined in cases rehabilitating after low back pain. The questionnaire is structured into six questions each with a minimal score of 0 and maximum score of 5. A score from 0%-20% shows minimal disability, 21%-40 moderate disability, 41%-60% severe disability, 61%-80% crippled, and 81%-100% indicates the patient is either bed bound or exaggerating symptoms (Fairbank & Pynsent, 2000; Garg et al., 2020). It has been translated into multiple native languages for easy understanding by the patient. It is also commonly used in clinical practice not only for low back pain but also other conditions such as infections of the spine, spondylosis, spondylolisthesis and prolapsed intervertebral disc (Garg et al., 2020).

The QBPDS is the third most popular questionnaire employed for assessment of low back pain in adults. It was designed, developed and validated by Kopec et al. It has been used to measure the level of functional disability in patients with low back pain. It contains 20 items that are structured into 6 different kinds of activities such as bed/rest (1-3), sitting/standing (4-6), ambulation (7-9), movement (10-12), bending or stooping (13-16), and handling of large or heavy objects (17-20). Each item begins with the statement “Do you have trouble with…?” The question statement is followed by a twenty different activities with six categories. The answers are recorded using the Likert scale (0=no effort; 5= not able to). The values are summed up and the score (0-100) is evaluated for degree of functional disability (Kopec et al., 1996).

Critical review of the different tools has revealed that the generic tools with high validity and reliability are the Brief Pain Inventory (BPI) and McGill Pain Questionnaire (MPQ). The BPI and MPQ can be used in cases of acute and chronic pain each with its own benefits. The BPI is a 15-item questionnaire that assesses pain intensity and interference with physical activities. The MPQ has 22 items which are inclusive of neuropathic pain assessment (Garg et al., 2020).

Non-specific low back pain is the most common form of low back pain. Around 90% of low back pain cases that present to the primary care physician fall into this category. Because no known cause is associated with this type of back pain, a triage approach is employed to exclude other serious pathologies (Maher, Underwood, & Buchbinder, 2016). In the Japanese population the prevalence of chronic non-specific low back pain is lower (15.5%). According to their healthcare insurance plan, all cases of low back pain are seen directly by an orthopedist. The study revealed an increased prevalence of chronic non-specific low back pain among people in their 50's (27.4%) (Iizuka et al., 2017).

Imaging has no significant role in the diagnosis of non-specific low back pain, unless there is suspicion of an underlying disease. According to the American College of Physicians' guideline imaging should not be delayed if serious pathology is suspected such as cancer, cauda equina syndrome or spinal infection. In cases of spondyloarthritis, vertebral compression fracture, radiculopathy or spinal compression with weak risk of cancer, the guidelines advise a delay in imaging with trial of therapy. Most commonly the MRI is used for diagnosis of non-specific low back pain. Review of data has revealed that imaging does not help in prediction of possible episode of back pain. Erroneous imaging increases patient exposure to unnecessary radiation with high possibility future harmful effects (Maher et al., 2016).

Management of cases with non-specific low back pain is a two-step procedure. The primary focus is the reduction of pain followed by rehabilitation to prevent disability. Review of different guidelines has revealed some points of similarities in the management protocols. Patient education and counselling, reassurance, medicinal pain relief, non-pharmacologic therapy, individualized follow-up routine, and assessment of prognosis are included in the management guidelines. The guidelines also state that after a thorough clinical assessment conducted by the primary care clinician, the patient should then be explained that a medically serious cause for their symptoms are unlikely and why imaging is not necessary. Identification and clarification of patient misconceptions has been deemed important to prevent fear related avoidance beliefs and expectations of poor recovery by the patient. Emphasis on patient education has positive outcomes in return to work (Maher et al., 2016).

CHAPTER 3

METHODOLOGY

3.1 STUDY DESIGN:

Case control study

3.2 PARTICIPANTS:

Cases: Patients of both genders, ages 18-65 years having acute and chronic low back pain.

Controls: asymptomatic patients matched with cases

3.3 SETTING:

The study was conducted at the Radiology Department of PNS Shifa Hospital and Advanced Radiology Clinic, Karachi

3.4 INCLUSION CRITERIA:

(a) For cases

- Males and females between the ages of 18-65 years
- Diagnosed cases of acute and chronic non-specific low back pain clinically examined and referred from the outpatient departments of PNS Shifa

(b) For controls

- Males and females between the ages of 18-65 years
- Patients presenting to outpatient departments of PNS Shifa and Advanced Radiology Clinic for X-Ray with no back pain

3.5 EXCLUSION CRITERIA:

- Patients with previous history of spinal surgery
- Fracture of sacrum
- Trauma to the back e.g road traffic accident, fall on back
- Pregnant women

- Rheumatoid arthritis
- Ankylosing spondylitis
- Diffuse skeletal hyperostosis

3.6 DURATION OF STUDY:

a) Individual study period: 2 hours
b) Total period of study: January-June 2020

3.7 SAMPLE SIZE CALCULATION:

Sample size was calculated using the method for “frequency in a population” on www.openepi.com. Population size of 400 and hypothesized frequency of 29.45% was used for the calculation (Arooj et al., 2018) with margin of error of 5% and confidence interval of 95%. The required sample for cases and control groups was 89 respectively. Total sample size was 178.

3.8 SAMPLING TECHNIQUE:

Sampling was done using the non-probability convenience sampling technique.

3.9 HUMAN SUBJECTS AND CONSENT:

Patients between the ages of 18 to 65 years presenting with complaints of back pain to the outpatient departments of rehabilitation medicine, orthopedic surgery and emergency medicine were assessed by the consultants and residents. Detailed history and clinical examination was performed in each case to rule out a serious pathology. Patients were explained the purpose of the study and enrolled if they signed the informed consent form. The enrolled participants were advised X-ray of the lumbosacral spine anteroposterior and lateral views for morphometric measurements of the sacral hiatus. The X-ray of the lumbosacral region was performed on the Toshiba Rotanode system. The controls after giving informed consent were recruited from amongst the asymptomatic patients presenting to the radiology department from the other specialties for the purpose of medical review.

3.10 MATERIALS

Demographic information including gender, age, marital status, height (cm), weight (kg), BMI and occupation was recorded in the subject evaluation proforma for both cases and controls. Measurements of height and weight were applied to the formula (weight (kg)/height (m^2)) for calculation of the Body Mass Index. For the cases group details regarding history of low back pain were recorded such as the duration of symptoms, frequency of pain, activity associated with onset of pain, activities associated with pain aggravation, disturbance of sleep due to pain, need of frequent rest for pain relief, use of back care equipment. For the controls and cases questions regarding exercise routine (if any) were included in the proforma (Appendix). Responses were documented by the principal investigator.

3.10.1 Stadiometer

The subject height (cm) and weight (kg) were measured with the Body Weight and Health Scale (ZT-120) at the Rehabilitation Medicine Department of PNS Shifa Hospital using the stadiometer (Fig 3.10.1).

BMI was categorized according to the WHO guidelines as underweight, normal or healthy, overweight (pre-obese), obese class I, obese class II, and obese class III.

- Underweight: BMI values of <18.5 kg/m^2
- Normal: BMI values ranging from 18.5 till 24.9 kg/m^2 are considered healthy or normal.
- Overweight: BMI values from 25 to 29.9 kg/m^2 have been classified as overweight or pre-obese.
- Class I Obesity: BMI values ranging from 30 to 34.9 kg/m^2
- Class II Obesity: BMI values from 35 till 39.9 kg/m^2
- Class III Obesity: BMI values of $\geq$ 40 kg/m^2 are considered morbidly obese.

Fig.3.10.1 Stadiometer, height and weight measurement (PNS Shifa, Karachi)

3.10.2 Toshiba Rotanode TM Medical X-Ray Machine linked to Agfa Fuji PAC System

Anteroposterior and lateral views radiographic images of the lumbosacral spine were obtained through the Toshiba Rotanode X-Ray machine (Fig 3.10.2a). The images were transferred via the Agfa Fuji Pacs System (Figure 3.10.2b). Metric and non-metric parameters were measured using the Synapse digital image management system (Fujifilm Medical Systems, Tokyo, Japan). The effective dose at the time of exposure was kept at the minimum level necessary (0.1mVs) (Watson and Jones, 2018). The Computed Radiography system provides better quality radiographs as compared to the conventional radiography technique. The images were sought at higher kVp (kiloVoltage peak) and lower mAs (milliampere second) with potential reduction in the patient radiation dose. Furthermore the CR system was automatic and the imaging plates were reusable. In comparison to MRI, it had lower dose of radiation

Fig 3.10.2a Toshiba Rotanode X-Ray Machine Radiology Department of PNS Shifa, Karachi

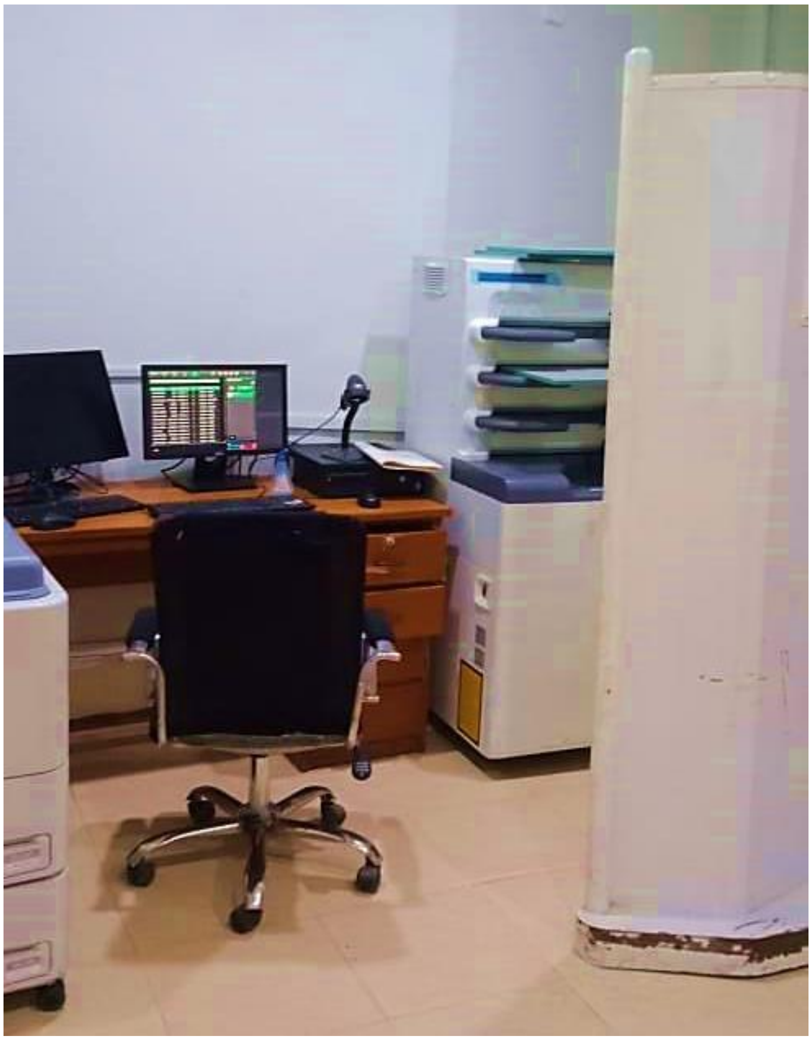


Fig.3.10.2b Agfa Fuji Pacs CR System, showing C.P.U, monitor, printer and cassette reader (Radiology Dept, PNS Shifa hospital, Karachi)

3.11 PARAMETERS OF STUDY

The parameters included in the study were demographic, physical characteristics, factors related to low back pain and the anatomic features of the sacral hiatus.

3.11.1 Demographic

It included information regarding the gender, age, marital status, and occupation.

3.11.2 Physical Characteristics

These were the height (cm), weight (kg) and BMI.

3.11.3 Low Back Pain Related Factors

These included the duration, frequency, associated physical activity, aggravating factors, need for frequent rest, sleep disturbance, disruption of daily activities, and use of back care equipment.

3.11.4 Level of Physical Activity

It was assessed by the frequency of exercise (every day to once a month).

3.11.5 Anatomic Features of the Sacral Hiatus

These were observed on the anteroposterior and lateral radiographic images of the lumbosacral spine. The parameters were further divided into two groups:

A. Non-Metric

These were observed on the anteroposterior view of the lumbosacral spine x-ray.

- Shape of sacral hiatus
- Level of apex of sacral hiatus with respect to the sacral vertebra
- Level of base of sacral hiatus with respect to the sacral vertebra

B. Metric

These were measured using the Synapse software. Anteroposterior view of the lumbosacral spine was used to measure the length and transverse diameter of the hiatus and the lateral view was used for measurement of the depth (anteroposterior diameter).at the apex of the hiatus.

- Length of sacral hiatus measured in millimeters
- Transverse width of sacral hiatus measured in millimeters
- Antero-posterior diameter of sacral hiatus measured in millimeters

3.12 PROTOCOL OF THE STUDY

Ethical review committee approval was obtained from Bahria University Medical and Dental College (BUMDC) and Advanced Radiology Clinic (ARC). Adult patients presenting with complaints of low back pain fulfilling the inclusion criteria were selected. After detailed history and physical examination at the outpatient departments of rehabilitation medicine, orthopedic surgeon and emergency medicine at the PNS Shifa Hospital and Advanced Radiology Clinic, Karachi, participants were enrolled in the study. Subjects were informed about the preparation protocol for the lumbosacral X-ray. Written informed consent was taken from the participants (Appendix). Information regarding age, gender, marital status, occupation, height (cm), weight (kg), calculated BMI, factors related to low back pain such as the duration, frequency, associated physical activity, aggravating factors, need for frequent rest, sleep disturbance, disruption of daily activities, use of back care equipment and the level of physical activity (exercise) according to the frequency of exercise was recorded by the principal investigator in the subject evaluation proforma.

3.12.1 Imaging and Patient Positioning

Radiographic images of the lumbosacral spine in anteroposterior and lateral views showing the entire 5th lumbar vertebra, symphysis pubis and both sacroiliac joints were utilized for the observation of the anatomic features of the sacral hiatus. The subject was provided protection from unnecessary radiation with metal free gown. Furthermore scatter radiation and chances of clothing artifact were reduced by four sided collimation. ALARA protocol as described by Munroe (2004) was followed for reduction in radiation.

Radiographs of the subject were obtained by the Toshiba Rotanode^{TM} medical X-ray imaging machine. For the anteroposterior views the subject was in supine position with legs extended and for the lateral view the subject was positioned in lateral position with knees flexed. The distance from the anterior superior iliac spines to the image receptor was kept equal to avoid rotation and give a symmetrical view of the sacrum and sacroiliac joints. The exposure factor for the x-ray ranged from 75-90 kVp (kilovoltage). The milliamperage second (mAs) was adjusted according to the kilovoltage. Angling of the central was applied in the cephalic direction at 15° so that the central ray entered the pelvis at the midsagittal plane midway between anterior superior iliac spine and the symphysis pubis. This angle was used to reduce the possibility of sacral foreshortening by keeping the posterior sacral foramina open.

3.12.2 Assessment of Hiatal Parameters

The radiographic images were visualized using the Synapse software and assessed by classified radiologist for age related degenerative changes, lumbosacral transitional vertebrae, reduced disc spaces and sacral fractures. After selection of the appropriate radiographs, the anatomical landmarks for location of the sacral hiatus were the identified. Using the anteroposterior radiographs, the sacral hiatus was then localized inferior to the median sacral crest as the gap seen at the caudal end of the sacrum. Then the parameters were assessed by the principal investigator.

A. Non-metric Parameters

The non-metric parameters of the sacral hiatus included the shape, level of apex and level of base. These were observed with the naked eye.

(i) Identification of Hiatal Shape

The shape of the hiatus was identified according to the articular margins on either side of the hiatal opening. The opening of the hiatus was assessed for the different shapes, dorsal wall defects or absence. Six different shapes were noted based on the description from the previous study done by Vedapriya et al (2013). To accurately identify the shapes of the hiatal opening the following guideline was used:

- Inverted ‘U’: hiatus appears U shaped with apex above and base below
- Inverted ’V’: hiatus has V shaped appearance with apex above and base below
- Irregular: boundaries of the hiatus do not appear smooth or when there is a unilateral projection
- Dumbbell: projections from both sides of the hiatus at the same level
- Bifid: lamina of the sacral vertebra appear unfused above the fused part
- M: a downward projection in the midline indents the apex
- Absent hiatus: all the lamina of the sacral vertebra appear fused, no opening can be seen

(ii) Level of Apex of the Hiatus

The apex was identified as the highest point of the hiatal opening immediately below the median sacral crest. The level of the apex was then ascertained with reference to level of the sacral vertebra at which it was observed (S1-S5).

(iii) Level of Base of the Hiatus

To identify the base, the sacral cornua were first located. The area between them was noted as the base. The level of the base was documented with reference to the level of the sacral or coccygeal vertebra at which it was seen (S3-coccyx).

B. Metric Parameters

The metric parameters (length of sacral hiatus, anteroposterior diameter and transverse width) were measured in millimeters with digital ruler in the Synapse software. The observations were cross-checked by the classified radiologist and then documented on the respective subject evaluation proforma.

(i) Hiatal Length

Markers were placed at the apex and midpoint of the hiatal base. The vertical distance between the two markers was measured in millimeters and recorded in the respective proforma.

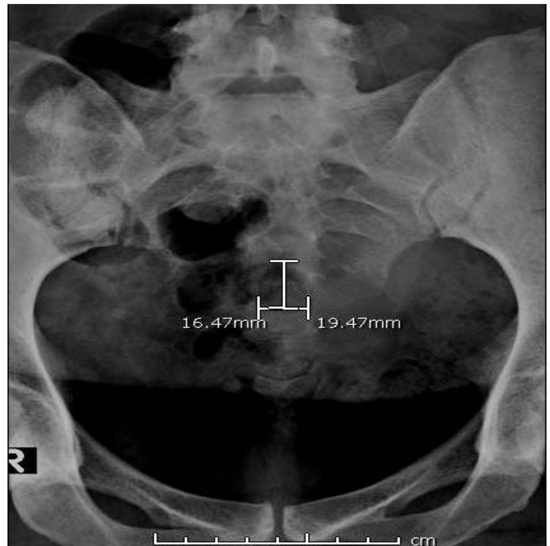
(ii) Transverse Width

The sacral cornua were identified on each side of the base. Markers were placed at the cornua. Then the horizontal distance between the cornua was measured in millimeters and recorded in the proforma.

(iii) Anteroposterior Diameter

It was measured on the lateral radiographs of the lumbosacral spine. The apex of the hiatus was first identified and marked. Then the depth was measured in millimeters from the apex till the anterior wall of sacral canal. Findings were recorded in the proforma.

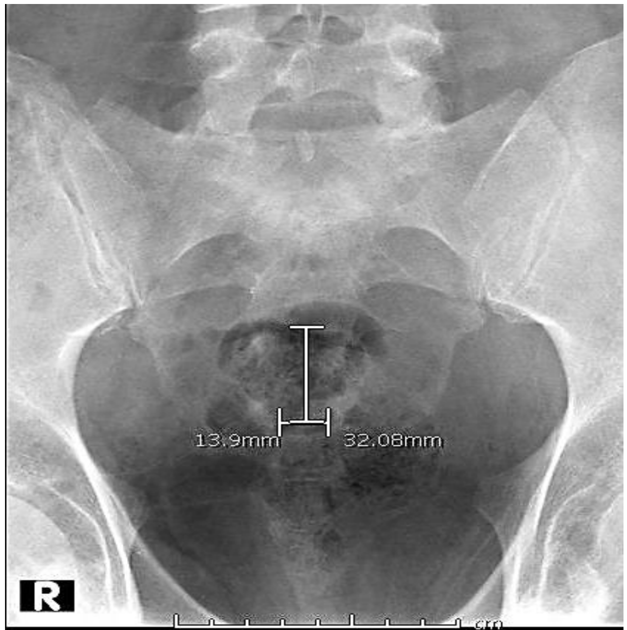
A. Inverted V Shaped



B. Inverted U Shaped Hiatus

C. Irregular Hiatus

D. Dumbbell Shaped Hiatus



E. M-shaped Hiatus

F. Bifid Hiatus

Fig. 3.12.2a X-ray of LS Spine AP view showing the hiatal shapes observed; A: Inverted V; B: Inverted U; C: Irregular; D: Dumbbell; E: M-shaped; F: Bifid (Courtesy of Advanced Radiology Clinic, Karachi)

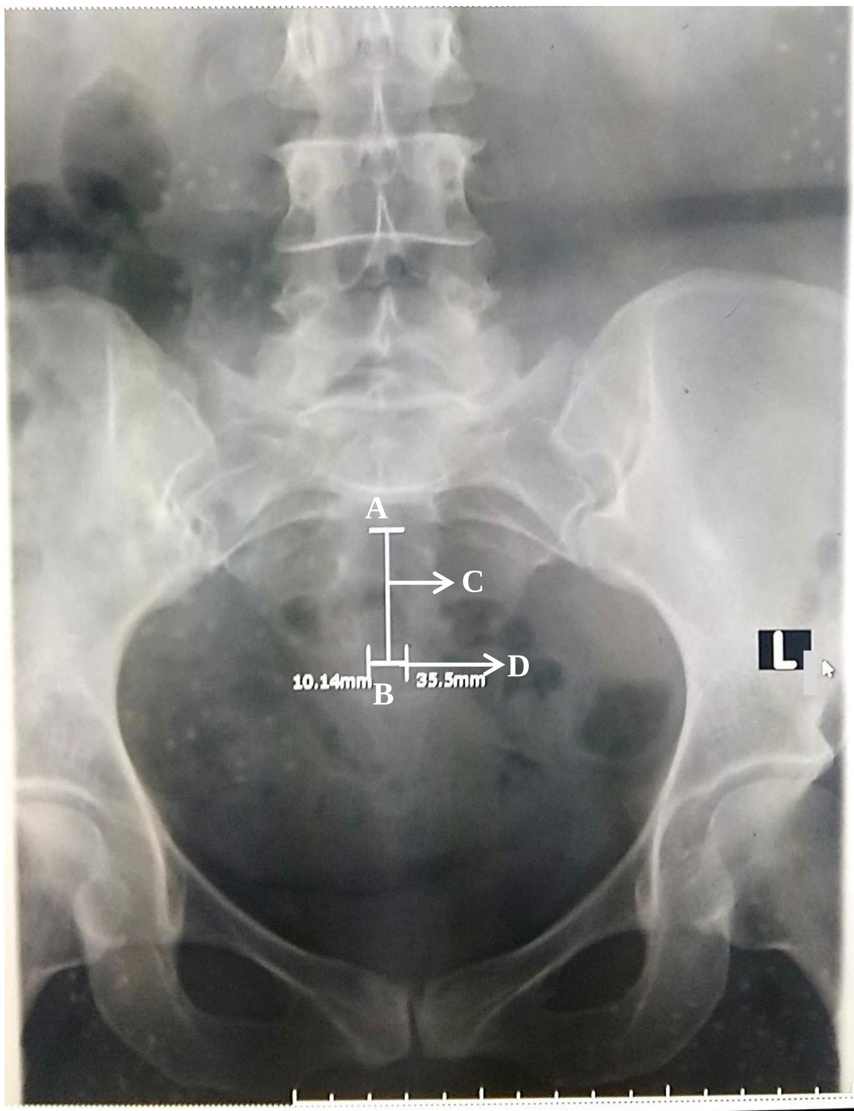


Fig. 3.12.2b X-ray of LS Spine AP view; A: Apex; B: Base; C: Length and D: Transverse width (Courtesy of PNS Shifa Hospital, Karachi)

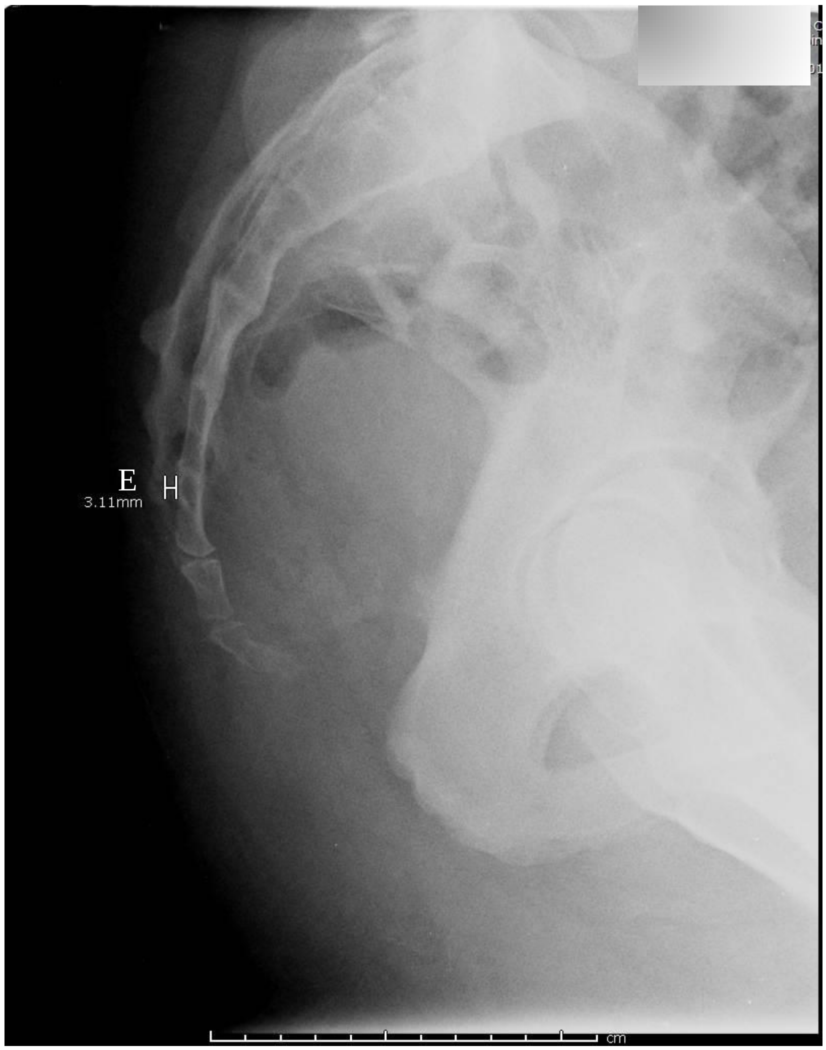
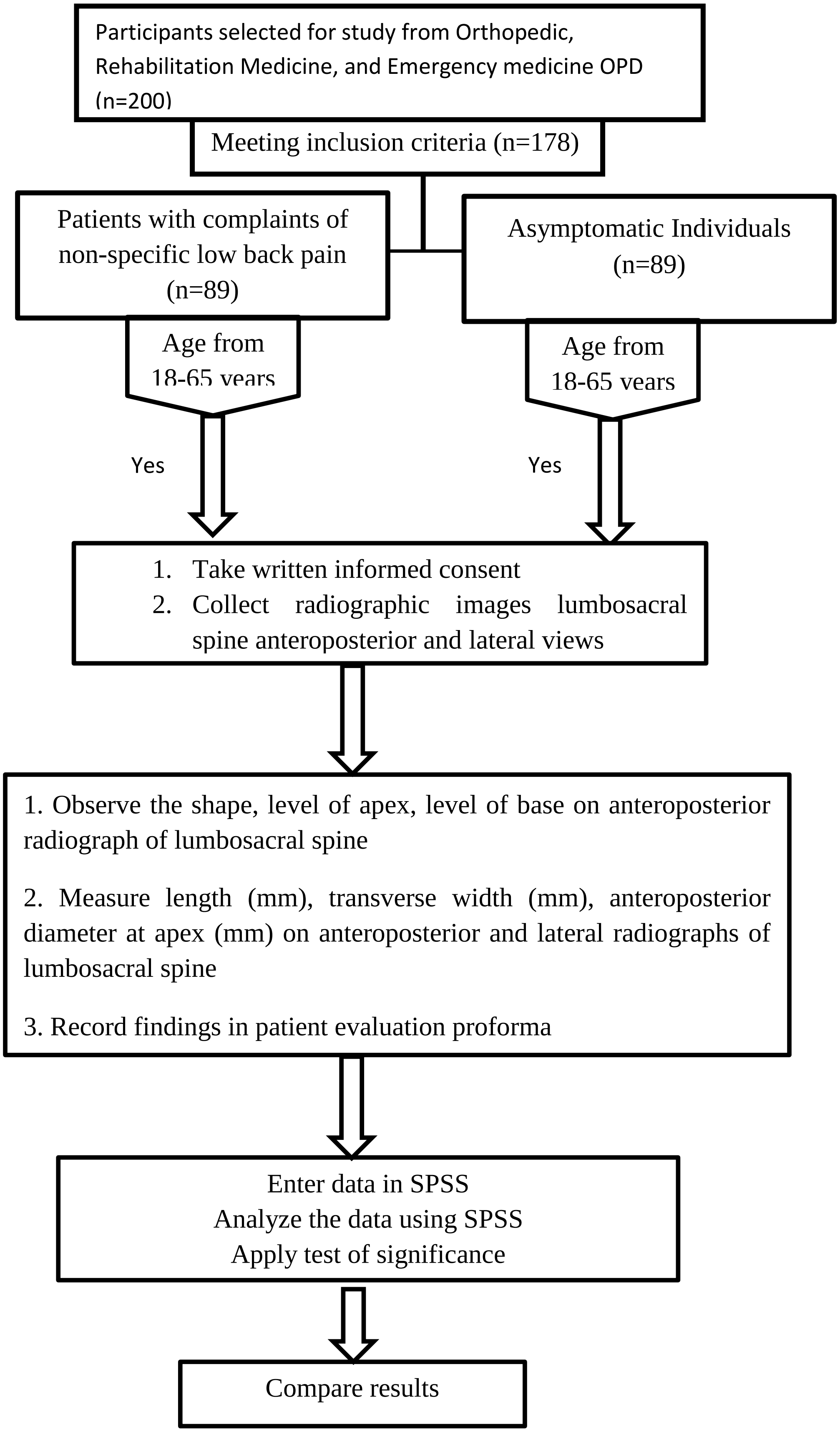


Fig 3.12.2c X-ray of Lumbosacral spine lateral view E: Anteroposterior diameter (Courtesy of Advanced Radiology Clinic, Karachi)

3.13 ALGORITHM OF THE STUDY



3.14 STATISTICAL ANALYSIS

SPSS version 23.0 software was used for the data analysis. Mean, median, mode and standard deviation was determined for the continuous variables. Graphs, frequency and percentage tables were used to represent the categorical variables. To determine relationship between the categorical variables the Chi-square and Fisher exact tests were applied. The independent sample T-test was applied to compare the two groups. The one-way ANOVA test was applied for comparison of more than two groups. The difference was considered statistically significant for p-value ≤ 0.05. Binary logistic regression analysis was also used to ascertain the risk of association between the variables.

CHAPTER 4

RESULTS

The current study was constructed to identify the variations in the anatomy of the sacral hiatus in the lumbosacral radiographs of non-specific low back pain patients, compare these findings with individuals without back pain and determine a correlation between occurrence of low backache with the hiatal variations as well as age, BMI, marital status, occupation, height and weight. The results were displayed in tables as well as graphical representations.

4.1 COMPARISON OF SHAPE OF SACRAL HIATUS BETWEEN CASES AND CONTROLS

In the study six different hiatal shapes were observed in the radiographic images of cases and controls. These were: inverted 'U', inverted 'V', 'M' shape, dumbbell, irregular and bifid.

In cases the inverted 'U' shape was most common (47; 52.8%), followed by the inverted 'V' (25; 28.1%), dumbbell (5) and irregular (5) (5.6% each), 'M' shape (4; 4.5%) and bifid (3; 3.4%) (Fig. 1) (Table1a).

In the control group the most commonly observed shape was the inverted 'V' (45; 50.6%) followed by inverted 'U' (29; 32.6%), dumbbell (5) and irregular (5) (5.6% each), bifid (3; 3.4%) and 'M' shape (2; 2.2%) (Table1b).

The differences in the shapes between cases and controls were statistically significant with p-value of 0.047 (Table 1b).

4.2 COMPARISON OF LEVEL OF APEX OF SACRAL HIATUS BETWEEN CASES AND CONTROLS

The level of apex was determined on visual inspection of anteroposterior radiographic images of the lumbosacral spine. Findings were recorded with reference to the sacral vertebrae (Table 2).

In order of frequency the level of apex observed in the cases was at S3 (43; 48.3%), S2 (37; 41.6%), S4 (6; 6.7%) and S1 (3; 3.4%).

In the control group the apex was most commonly present at level of S3 (65; 73.0%), S2 (18; 20.2%), S4 (5; 5.6%), and S1 (1; 1.1%).

The differences observed between the level of apex in the cases and control groups were statistically significant with a p-value of 0.004.

4.3 COMPARISON OF LEVEL OF BASE OF THE SACRAL HIATUS BETWEEN CASES AND CONTROLS

The level of base was observed on visual inspection of the sacral hiatus in anteroposterior radiographic images of the lumbosacral spine with reference to the sacral and coccygeal vertebrae. In the cases the base of the highest level of the sacral hiatus base was at S3 (4) and lowest level was at coccyx (2). The base was most frequently seen at level of S5 (66.3%) followed by S4 (27.0%), S3 (4.5%) and coccyx (2.2%).

In the control group the highest level of the base of the sacral hiatus was at S3 (3) and lowest level was at first coccygeal vertebra (2) as well. In the order of frequency the level of base in the controls was observed at S5 (71.9%), S4 (22.5%), S3 (4.5%) and coccyx (2.2%).

The differences between the two groups were statistically nonsignificant with a p-value of 0.892 (Table 3).

4.4 COMPARISON OF HIATAL LENGTH BETWEEN CASES AND CONTROLS

The length of the hiatus was measured from the apex to the midpoint of the base on the anteroposterior radiographic images of the lumbosacral spine.

The mean hiatal length in the cases and controls was 30.09$\pm$10.02mm and 23.58$\pm$ 7.57mm respectively. The difference in the two groups was highly significant with a p-value less than 0.001 (Table 4).

4.5 COMPARISON OF ANTEROPOSTERIOR DIAMETER BETWEEN CASES AND CONTROLS

The anteroposterior diameter of the hiatus was measured in the lateral radiographic images of the lumbosacral spine at the apex of the hiatus. The mean depth in the cases was 3.38±2.05mm and 3.06±1.28mm in controls. The difference in the groups was not significant with a p-value of 0.215 (Table 4).

4.6 COMPARISON OF TRANSVERSE DIAMETER BETWEEN CASES AND CONTROLS

The transverse diameter was determined by measurement of the distance between the sacral cornua on anteroposterior radiographic images of the lumbosacral spine. The mean width of the hiatus in cases was 13.34±4.33mm and 11.76±3.51mm in controls. The difference was significant with p-value of 0.008 (Table 4).

4.7 COMPARISON OF HIATAL SHAPE, APEX AND BASE BETWEEN MALE AND FEMALES CASES

Different shapes of the hiatus were seen amongst the male and female cases (Fig). The most frequently observed shape in both genders was the inverted U in 42.4% males and 58.9% females followed by the inverted V which was observed in 39.4% males and 21.4% females. In the males the other shapes observed were the irregular (9.1%), dumbbell (6.1%), and M (3.0%). In female cases the M, dumbbell and bifid shapes were observed equally (5.4%) whereas the irregular shape was least common (3.6%). The variations in the shapes of hiatus within the cases compared between the genders were statistically nonsignificant: p-value of 0.254 (Table 5).

The level of apex of the hiatus was most commonly observed at S3 in male (54.5%) and at S2 (46.4%) in female cases. The second most common location in males was S2 (33.3%) and in females it was S3 (44.6%). The apex was also observed at S4 (males: 6.1%; females: 7.1%) and least frequently at S1 (males: 6.1%; females: 7.1%). The differences in the location of the apex between the genders were statistically nonsignificant with a p-value of 0.472 (Table 6).

The base of the hiatus in the 60.6% of male and 69.6% of female cases was commonly observed at level of S5. The second most common level was S4 in both genders (males: 30.3% and females: 25.0%). The lowest level of base in male cases was the coccyx (6.1%) whereas it was not seen at this level in female cases. The highest and least common level of base observed in the females was S3 (5.4%). The differences in the level of the base between genders were not significant with a p-value of 0.286 (Table 7).

4.8 COMPARISON OF HIATAL LENGTH, WIDTH AND DEPTH WITHIN CASES BETWEEN MALES AND FEMALES

In this study the comparison between the length and anteroposterior diameter as well as transverse width of the sacral hiatus was compared between the males and females with symptoms of low back pain to determine whether the differences were statistically significant (Table 8).

The average hiatal length in male cases was 33.5mm±9.74mm and in female cases was 29.94±10.26mm. The difference between genders was statistically nonsignificant with a p-value of 0.857.

Anteroposterior diameter of the hiatus in the cases had mean value of 3.21± 1.18 in male and 3.47± 2.42mm in female cases. The difference between male and female cases was not significant (p=0.571).

The mean transverse width in the male cases was 13.63±4.38mm and 13.17± 4.33mm in female cases. The difference between the genders was statistically nonsignificant with a p-value of 0.632.

4.9 COMPARISON OF NON-METRIC HIATAL PARAMETERS WITHIN CASES BETWEEN DIFFERENT AGE GROUPS

In the study the prevalence of the hiatal shapes observed in the cases were compared amongst the different age groups (Table 9). Data revealed that the most common shape in all age groups were the inverted ‘U’ and inverted ‘V’. Variable frequencies of hiatal shapes were observed in the different age groups with nonsignificant difference (p=0.886).

The apex of the hiatus was commonly observed at the level of S3 in all of the age groups followed by S2. Apex was not observed at level of S1 or S4 in the 18-25 years age group. The observed difference between the age groups was not significant (p=0.172) (Table 10).
The base of the hiatus was most commonly visualized at the level of S5 and S4 in all of the age groups. Variable incidence of base at S3 and coccyx was observed in the ages 26-35, 36-45 and 56-65 years. Nonsignificant difference between the age groups was found (p=0.886) (Table 11).

4.10 COMPARISON OF METRIC HIATAL PARAMETERS WITHIN CASES BETWEEN DIFFERENT AGE GROUPS

In this study the ages of the cases ranged from 18-65 years. The cases were divided into 5 equal groups. Each metric parameter of the sacral hiatus was analyzed for each age group to determine any significant difference in hiatal anatomy with age (Table 12).
The longest average hiatal length was observed in the age groups 46-55 years (31.79±10.42mm) and 36-45 years (31.59±10.88mm) with minor variations. The shortest average hiatal length was recorded in the 18-25 years (23.15± 3.53mm) age group. The differences in the mean length of the sacral hiatus amongst the different age groups were statistically nonsignificant with a p-value of 0.23.
The average anteroposterior diameter of the sacral hiatus was the largest in the 36-45 years (3.91± 3.23mm) and the smallest in 18-25 years (2.98± 1.23mm) age groups. There was nonsignificant difference between the measurements of anteroposterior diameter with regards to age in the cases (p=0.567).
The widest sacral hiatus was observed in the 36-45 years (14.04± 4.93mm) and 46-55 years (13.85± 5.39mm) age groups. The smallest value was present in the 18-25 years (12.25± 1.80mm) age group. The differences in the transverse widths between the age groups were statistically nonsignificant with a p-value of 0.613.

4.11 DEMOGRAPHICS IN CASES AND CONTROLS

The study was conducted with permission at a private radiology clinic and tertiary care hospital. Amongst the 178 participants, there were 75 males (42.1%) and 103 females (57.9%) overall. The married group had 147 (82.6%) and unmarried group had 31 (17.4%)

subjects. The participants belonged to the age groups 18-25 (30; 16.9%), 26-35 (44; 24.7%), 36-45 (53; 29.8%), 46-55 (36; 20.2%), and 56-65 (15; 8.4%) years. The participants' occupation categories were retired (4; 2.2%), manual laborer (1; 0.6%), office worker (57; 32%), student (6, 3.4%), house wife (80; 44.9%), self-employed (2; 1.1%), field work (21; 11.8%) and other (7; 3.9%). There were 89 cases and 89 controls (Table 13).

The collected data revealed a high frequency of female (62.9%) cases as compared to males (37.1%) (Fig.2). Comparison with control group revealed statistical nonsignificant difference with p-value of 0.172 (Table 14).

According to the data collected the number of cases was remarkably high in married (81; 91.0%) as compared to unmarried (8; 9.0%) (Fig.3). Comparison with controls revealed significant results with a p-value of 0.003 (Table 15).

Comparison between the different age groups revealed the highest numbers of cases (27; 30.3%) in the age range of 36-45 years, followed by 26-35 (25; 28.1%), 46-55 (22; 24.7%), 18-25 (9; 10.1%) and 56-65 years (6; 6.7%) (Fig4). The difference between cases and controls was statistically nonsignificant with a p-value of 0.091 (Table 16).

The minimum recorded height in the cases was 152.40cm and the maximum height was 187.96 cm (Table 18). The average height in the cases was 164.64±7.95cm and 166.84±7.95cm in controls. Comparison revealed statistically nonsignificant difference between the groups (p=0.066) (Table 17).

The minimum weight recorded in the cases was 48kg and the maximum recorded value was 130kg (Table 17). The average weight in the cases was 72.67±13.28 kg and 62.65± 9.32kg in controls. Comparison showed statistically highly significant difference between the two groups (p<0.001) (Table 18).

BMI was calculated in both cases and controls using the recorded measurements of height and weight. After categorization as per WHO guidelines analysis of data revealed that 41.6% of cases were overweight (25-29.9), 36.0% normal (18.5-24.9), 16.9% belonged to obese class I (30-34.9), 3.4% were obese class III (>40) and 1.1% were underweight (<18.5). In the control group 86.5% participants had normal BMI, 6.7% were underweight and 6.7% overweight. The differences of BMI between the cases and controls were highly significant with p-value less than 0.001 (Table 19).

The occupation of the subjects was subdivided into retired, manual laborer, field worker, office worker, student, house-wife, self-employed and other categories. Analysis of data showed that a majority of the cases were home makers (51; 57.3%) and office workers (23; 25.8%) followed by field workers (9; 10.1%). There were 2 cases (2.2%) in self-employed category, 3 (3.4%) in other and 1(1.1%) in manual laborer group. No students or retired individuals were present in the cases group. On the other hand in the control group majority were office workers (34; 38.2%), house wives (29; 32.6%) and field workers (12; 13.5%). No student or retired individual reported with complaints of low back pain (Fig 5). The difference observed between the groups was significant (p = 0.003) (Table 20).

4.12 COMPARISON OF PHYSICAL ACTIVITY BETWEEN CASES AND CONTROLS

To rule out other possible associations of low back pain in this study the participant response to exercise was also recorded. Analysis of data showed that 80.09% of low back pain cases (72) did not exercise as compared to 62.9% of controls (56). A small number of cases (17; 19.1%) exercised as compared to a larger number of controls (33; 37.1%). Statistically significant difference in practice of physical activity amongst the two groups was determined (p=0.008) (Table 21).

The frequency of physical activity was also recorded. Amongst the cases 41.2% exercised two to three times a week, 35.5% daily, 11.8% once a week and 11.8% once a month. In the control group 60.6% exercised daily, 15.2% two to three times a week, 15.2% once a week and 9.1% once a month. Data analysis did not reveal significant difference in the frequency of exercise between the two groups (p=0.193) (Table 22).

4.13 COMPARISON OF BACK PAIN EXPERIENCE AMONGST CASES

In the study the duration of the low back pain was documented. Data revealed the highest prevalence of cases within one year (50 cases; 56.2%). It was followed by reports of complaints from 1-2 (19 cases; 21.3%), 3-4 (7 cases; 7.9%), and more than 4 years (13 cases; 14.6%) (Table 23).

Assessment of frequency determined a high number of cases with pain that occurred all the time (42 cases; 47.2%) followed by 2-3 times during the day (19 cases; 21.3%) and off and on (12 cases; 13.5%). Other responses recorded in order of frequency were once a day (8 cases, 9%), occasionally (4 cases; 4.5%), early morning (2 cases; 2.2%) and constantly (1 case; 1.1%) (Table 23).

Disruption of daily activities was noted in 80 cases (89.9%) while 9 cases (10.1%) had no problems with everyday routine. Sleep disturbance due to pain was recorded in 28 cases (31.5%). On the other hand 61 cases (68.5%) had no trouble with sleep. 86 cases (96.6%) reported need for frequent rest due to the pain while 3 cases (3.4%) did not require rest. 44 cases (49.4%) experienced difficulty in getting up from a chair and 41 cases (47.2%) had no difficulty (Table 23).

In the study the low back pain cases were assessed on the basis of activity that aggravated the pain. The documented answers revealed highest frequency of pain with physical activity in 33 cases (37.1%) with male female cases of 9 (27.3%) and 24 (42.9%) respectively. It was followed by bending (13 cases (14.6%); males (4; 12.1%) and females (9; 16.1%). Other activities observed in order of frequency were prolonged standing (10 cases; 11.2%), prolonged sitting (8 cases; 9%), walking (7 cases; 7.9%), house work and bending/praying/walking (5 cases; 5.6% each), sudden onset with no particular reason (4 cases; 4.5%), lifting weights (3 cases; 3.4%) and praying (1 case; 1.1%). The difference between the activities was significant (p= 0.016) (Table 24).

4.14 RELATIONSHIP BETWEEN THE SACRAL HIATAL PARAMETERS AND LOW BACK PAIN

To ascertain a relationship between the variations of the sacral hiatus parameters and complaints of low back pain binary logistic regression analysis in the cases was performed (Table 25).

Analysis of the different shapes of the hiatus revealed that the inverted ‘U’ (O.R= 1.621; C.I: 0.432-6.086) and ‘M’ shapes (O.R= 2; C.I: 0.244-16.362) had a positive association with low back pain. The odds of developing low back pain were equal in dumbbell (O.R= 1; C.I: 0.173-5.772), and bifid (O.R=1; C.I: 0.132-7.570) shapes. The inverted ‘V’ shape showed no association with development of low back pain (O.R= 0.556; C.I: 0.147-2.106).

The level of apex at the levels of S1 (O.R=2.5; C.I: 0.194-32.194) and S2 (O.R= 1.713; C.I: 0.460-6.372) showed risk of development of low back pain. No significant risk was found with apex at level of S3 (O.R= 0.551; C.I: 0.158-0.920).

The base of the hiatus at S3 (O.R= 1.33; C.I: 0.113-15.704) and S4 (O.R=1.2; C.I: 0.155-9.301) showed risk of low back pain. No significant risk was found with base at S5 (O.R= 0.92; C.I: 0.126-6.755).

Comparison of risk of low back pain with variations of hiatal length, transverse width and anteroposterior diameter was performed in the study (Table 26). It was found that in the cases the risk of low back pain in relation to hiatal length was 0.87 times higher than in controls (odds ratio: 1.087; C.I:1.047-1.128). This difference was highly significant (p <0.001).

Low back pain risk was also detected for transverse width in the cases (O.R= 1.123; C.I: 0.931-1.354). An increase in risk by 1.24 times was detected in the cases compared to controls.

Variations in anteroposterior diameter also showed an increased risk of low back pain in cases as compared to controls. The odds of low back pain in cases were 1.1 times more as compared to controls (O.R= 1.11; C.I: 1.025-1.204). The difference in the groups was significant (p = 0.01).

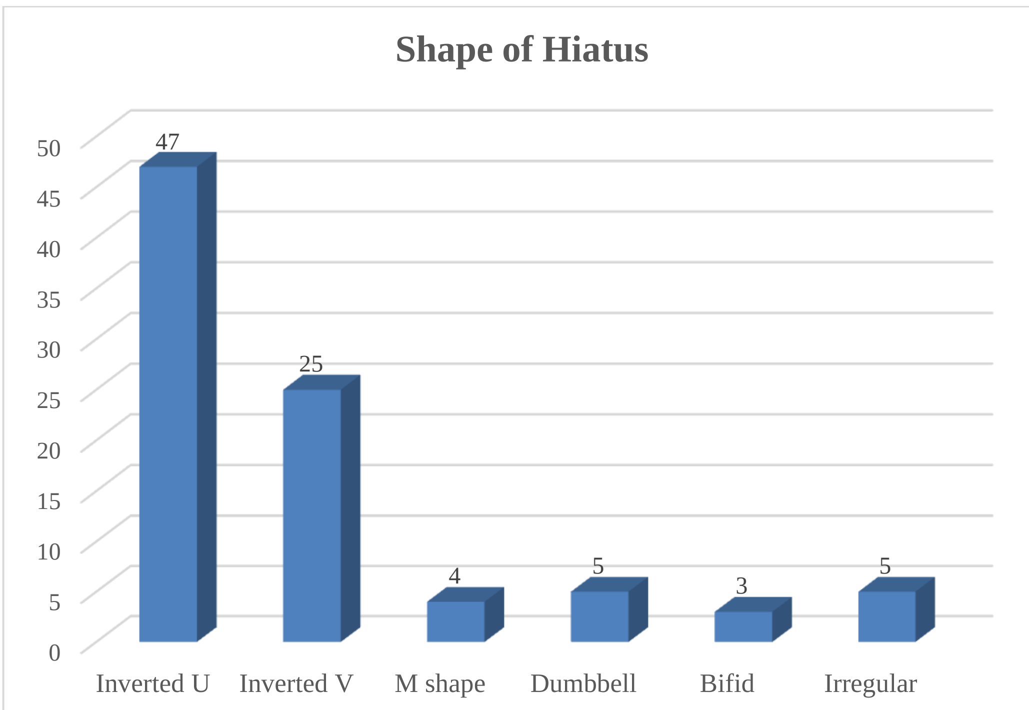


Fig 1: Bar Chart Demonstrating the Number of Sacral Hiatus Shapes in Low Back Pain Cases (n=89)

Table 1a

Number and Percentage of Sacral Hiatus Shapes in Cases (n=89)

Responses of Individuals with Low Back Pain (n=89)		
Shape of Hiatus	Number	Percent
Inverted U	47	52.8
Inverted V	25	28.1
M shape	4	4.5
Dumbbell	5	5.6
Bifid	3	3.4
Irregular	5	5.6
Total	89	100.0

Data is presented as number and percentages; n=Number of cases

Table 1b

Comparison of Shape of Sacral Hiatus between Cases and Controls (n=178)

Shape of Hiatus	Case (n=89)	Control (n=89)	Total	p-value
Inverted U	47 52.8%	29 32.6%	76 42.7%	**0.047***
Inverted V	25 28.1%	45 50.6%	70 39.3%	
M shape	4 4.5%	2 2.2%	6 3.4%	
Dumbbell	5 5.6%	5 5.6%	10 5.6%	
Bifid	3 3.4%	3 3.4%	6 3.4%	
Irregular	5 5.6%	5 5.6%	10 5.6%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 2

Comparison of Level of Apex between Cases and Controls (n=178)

Level of Apex	Case (n=89)	Control (n=89)	Total	p-value
1st sacral vertebra	3 3.4%	1 1.1%	4 2.2%	**0.004***
2nd sacral vertebra	37 41.6%	18 20.2%	55 30.9%	
3rd sacral vertebra	43 48.3%	65 73.0%	108 60.7%	
4th sacral vertebra	6 6.7%	5 5.6%	11 6.2%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 3

Comparison of Level of Base of Sacral Hiatus between Cases and Controls (n=178)

Level of Base	Case (n=89)	Control (n=89)	Total	p-value
3rd sacral vertebra	4	3	7	0.892
	4.5%	3.4%	3.9%	
4th sacral vertebra	24	20	44	
	27.0%	22.5%	24.7%	
5th sacral vertebra	59	64	123	
	66.3%	71.9%	69.1%	
Coccyx	2	2	4	
	2.2%	2.2%	2.2%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 4

Comparison of Hiatal Length, Anteroposterior Diameter and Transverse Width between Cases and Controls (n=178)

Parameters		Mean	SD	p-value
Hiatal length (mm)	Case	30.09	10.02	**0.000** **
	Control	23.58	7.57	
Antero-posterior Diameter (mm)	Case	3.38	2.05	0.215
	Control	3.06	1.28	
Transverse Width (mm)	Case	13.34	4.33	**0.008***
	Control	11.76	3.51	

p-value $\leq$ 0.05: statistically significant; *: significant: **: highly significant; Test applied: Independent sample T-test

Table 5

Comparison of Shape of Sacral Hiatus in Male and Female Cases (n=89)

Shape of Hiatus	Gender		Total	**p-value**
	Male	Female		
Inverted U	14	33	47	0.254
	42.4%	58.9%	52.8%	
Inverted V	13	12	25	
	39.4%	21.4%	28.1%	
M shape	1	3	4	
	3.0%	5.4%	4.5%	
Dumbbell	2	3	5	
	6.1%	5.4%	5.6%	
Bifid	0	3	3	
	0.0%	5.4%	3.4%	
Irregular	3	2	5	
	9.1%	3.6%	5.6%	
Total	33	56	89	
	100.0%	100.0%	100.0%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 6

Comparison of Level of Apex between Male and Female Cases

Level of Apex	Gender		Total	**p-value**
	Male	Female		
1st sacral vertebra	2 6.1%	1 1.8%	3 3.4%	0.472
2nd sacral vertebra	11 33.3%	26 46.4%	37 41.6%	
3rd sacral vertebra	18 54.5%	25 44.6%	43 48.3%	
4th sacral vertebra	2 6.1%	4 7.1%	6 6.7%	
Total	33 100.0%	56 100.0%	89 100.0%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 7

Comparison of Level of Base of Hiatus between Male and Female Cases

Level of Base	Gender		Total	**p-value**
	Male	Female		
3rd sacral vertebra	1 3.0%	3 5.4%	4 4.5%	0.286
4th sacral vertebra	10 30.3%	14 25.0%	24 27.0%	
5th sacral vertebra	20 60.6%	39 69.6%	59 66.3%	
Coccyx	2 6.1%	0 0.0%	2 2.2%	
Total	33 100.0%	56 100.0%	89 100.0%	

p-value <u><</u> 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 8

Comparison of Hiatal Parameters between Male and Female Cases (n=89)

Variables	Gender	Mean	SD	p-value
Hiatal length (mm)	Male	30.35	9.74	0.857
	Female	29.94	10.26	
Antero-posterior Diameter (mm)	Male	3.21	1.18	0.571
	Female	3.47	2.42	
Transverse Width (mm)	Male	13.63	4.38	0.632
	Female	13.17	4.33	

p-value ≤ 0.05: statistically significant; *:significant; Test applied: Independent Sample T-test

Table 9

Comparison of Hiatal Shape within Cases between Different Age Groups (n=178)

Shape of Hiatus	Age in Years					Total	p-value
	18-25	26-35	36-45	46-55	56-65		
Inverted U	4 44.4%	13 52.0%	14 51.9%	12 54.5%	4 66.7%	47 52.8%	0.886
Inverted V	3 33.3%	7 28.0%	9 33.3%	5 22.7%	1 16.7%	25 28.1%	
M shape	0 0.0%	1 4.0%	0 0.0%	2 9.1%	1 16.7%	4 4.5%	
Dumbbell	1 11.1%	2 8.0%	1 3.7%	1 4.5%	0 0.0%	5 5.6%	
Bifid	1 11.1%	0 0.0%	2 7.4%	0 0.0%	0 0.0%	3 3.4%	
Irregular	0 0.0%	2 8.0%	1 3.7%	2 9.1%	0 0.0%	5 5.6%	
Total	9 100.0%	25 100.0%	27 100.0%	22 100.0%	6 100.0%	89 100.0%	

p-value ≤ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 10

Comparison of Hiatal Apex within Cases between Different Age Groups (n=178)

Level of Apex	Age in Years					Total	p-value
	18-25	26-35	36-45	46-55	56-65		
1st sacral vertebra	0 0.0%	0 0.0%	1 3.7%	1 4.5%	1 16.7%	3 3.4%	0.172
2nd sacral vertebra	2 22.2%	13 52.0%	12 44.4%	7 31.8%	3 50.0%	37 41.6%	
3rd sacral vertebra	7 77.8%	8 32.0%	12 44.4%	14 63.6%	2 33.3%	43 48.3%	
4th sacral vertebra	0 0.0%	4 16.0%	2 7.4%	0 0.0%	0 0.0%	6 6.7%	
Total	9 100.0%	25 100.0%	27 100.0%	22 100.0%	6 100.0%	89 100.0%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 11

Comparison of Hiatal Base within Cases between Different Age Groups (n=178)

Level of Base	Age in Years					Total	p-value
	18-25	26-35	36-45	46-55	56-65		
3rd sacral vertebra	0 0.0%	1 4.0%	2 7.4%	0 0.0%	1 16.7%	4 4.5%	0.886
4th sacral vertebra	2 22.2%	6 24.0%	7 25.9%	7 31.8%	2 33.3%	24 27.0%	
5th sacral vertebra	7 77.8%	18 72.0%	17 63.0%	14 63.6%	3 50.0%	59 66.3%	
Coccyx	0 0.0%	0 0.0%	1 3.7%	1 4.5%	0 0.0%	2 2.2%	
Total	9 100.0%	25 100.0%	27 100.0%	22 100.0%	6 100.0%	89 100.0%	

p-value ≤ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

Table 12

Comparison of Metric Hiatal Parameters with Age (n=178)

Variables	Age in Years	Mean	SD	p-value
Hiatal length (mm)	18-25	23.15	3.53	0.23
	26-35	29.45	10.69	
	36-45	31.59	10.88	
	46-55	31.79	10.42	
	56-65	30.43	4.06	
	Total	30.09	10.02	
Antero-posterior Diameter (mm)	18-25	2.98	1.23	0.567
	26-35	3.26	1.21	
	36-45	3.91	3.23	
	46-55	3.18	1.22	
	56-65	2.76	1.09	
	Total	3.38	2.05	
Transverse Width (mm)	18-25	12.25	1.80	0.613
	26-35	13.22	3.31	
	36-45	14.07	4.93	
	46-55	13.85	5.39	
	56-65	10.41	3.07	
	Total	13.34	4.33	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: One-way ANOVA

Table 13

Demographic Characteristics of overall Participants (n=178)		
Gender	Number	Percent
Male	75	42.1
Female	103	57.9
Marital Status	Number	Percent
Married	147	82.6
Single	31	17.4
Age	Number	Percent
18-25	30	16.9
26-35	44	24.7
36-45	53	29.8
46-55	36	20.2
56-65	15	8.4
Occupation	Number	Percent
Retired	4	2.2
Manual laborer	1	.6
Office worker	57	32.0
Student	6	3.4
House wife	80	44.9
Self employed	2	1.1
Field work	21	11.8
Other	7	3.9
Group	Number	Percent
Case	89	50.0
Control	89	50.0
Low Back Pain	Number	Percent
Yes	89	50.0
No	89	50.0

Data presented as number and percentage

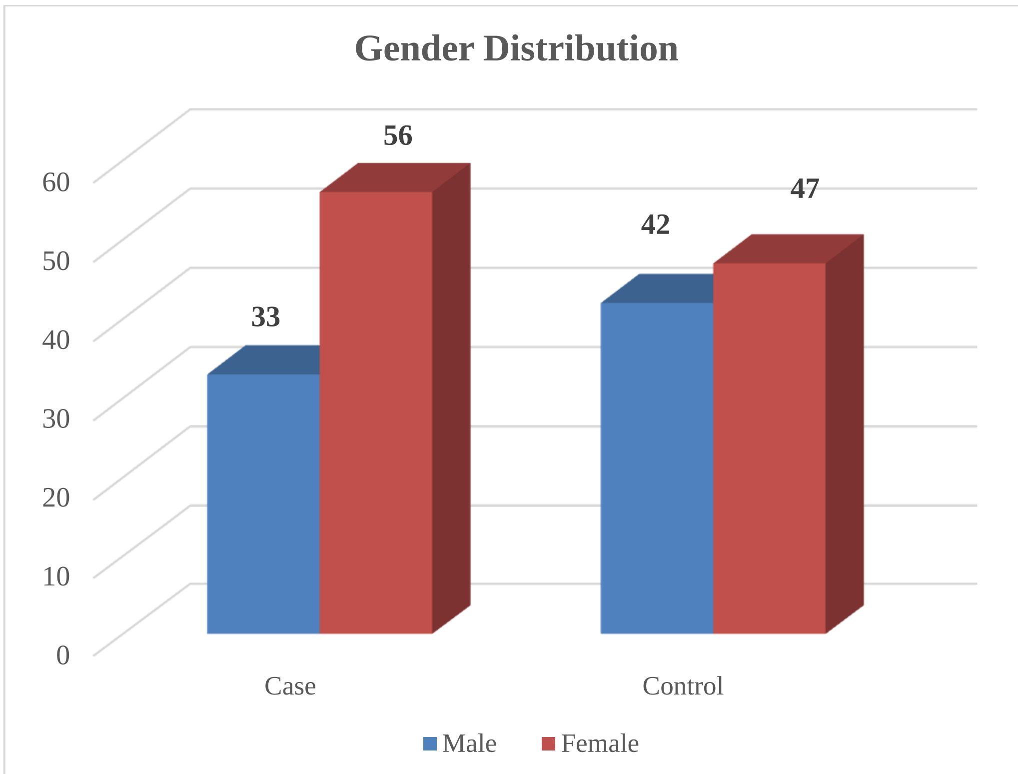


Fig 2. The comparison of gender in cases and control groups

Table 14

Comparison of Gender between Cases and Controls (n=178)

Gender	Case (n=89)	Control (n=89)	Total	p-value
Male	33 37.1%	42 47.2%	75 42.1%	0.172
Female	56 62.9%	47 52.8%	103 57.9%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Chi-square

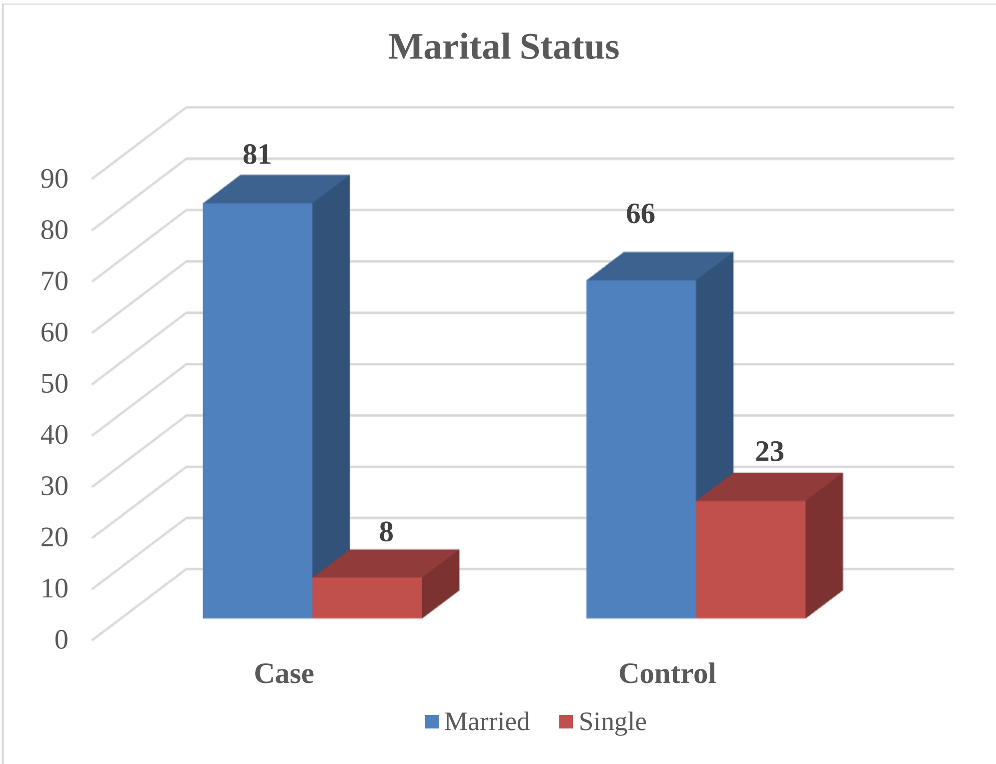


Fig 3. Bar Chart Demonstrating the Comparison of Marital Status between Cases and Controls (n=178)

Table 15

Comparison of Marital Status between Cases and Controls (n=178)

Marital Status	Case (n=89)	Control (n=89)	Total	p-value
Married	81 91.0%	66 74.2%	147 82.6%	**0.003***
Single	8 9.0%	23 25.8%	31 17.4%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Chi-square

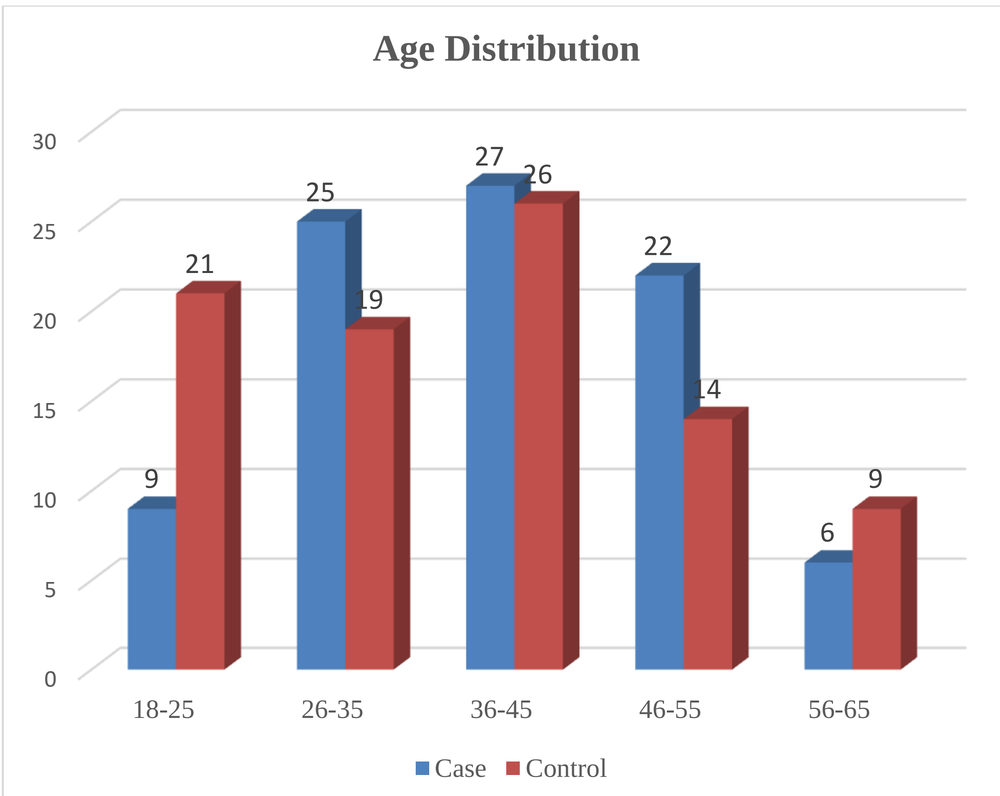


Fig.4. Bar Chart Demonstrating Comparison of Age between Cases and Controls (n=178)

Table 16

Comparison of Age between Cases and Controls (n=178)

Age (years)	Case (n=89)	Control (n=89)	Total	p-value
18-25	9 10.1%	21 23.6%	30 16.9%	0.091
26-35	25 28.1%	19 21.3%	44 24.7%	
36-45	27 30.3%	26 29.2%	53 29.8%	
46-55	22 24.7%	14 15.7%	36 20.2%	
56-65	6 6.7%	9 10.1%	15 8.4%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Chi-square

Table 17

Hiatal Parameters in Cases of Low Back Pain (n=89)				
Parameter	Minimum	Maximum	Mean	SD
Height (cm)	152.40	187.96	164.64	7.95
Weight (kg)	48.00	130.00	72.67	13.28
Hiatal length (mm)	10.21	57.23	30.09	10.02
AP Diameter (mm)	0.29	15.96	3.38	2.05
Transverse Width (mm)	0.00	27.10	13.34	4.33

Data presented as mean and standard deviation

Table 18

Comparison of Height and Weight between Cases and Controls (n=178)

Variables	**Group**	**Mean**	**SD**	**p-value**
Height (cm)	Control	166.84	7.95	0.066
	Case	164.64	7.95	
Weight (kg)	Control	62.65	9.32	**0.000****
	Case	72.67	13.28	

p-value $\leq$ 0.05: statistically significant; *: significant; **: highly significant; Test applied: Independent sample T-test

Table 19

Comparison of BMI between Cases and Controls (n=178)

BMI	Group		Total	p-value
	Control	Case		
Underweight (<18.5)	6 6.7%	1 1.1%	7 3.9%	**0.000****
Normal (18.5-24.9)	77 86.5%	32 36.0%	109 61.2%	
Overweight (25-29.9)	6 6.7%	37 41.6%	43 24.2%	
Obese Class I (30-34.9)	0 0.0%	15 16.9%	15 8.4%	
Obese Class II (35-39.9)	0 0.0%	1 1.1%	1 .6%	
Obese Class III (>40)	0 0.0%	3 3.4%	3 1.7%	
Total	89 100.0%	89 100.0%	178 100.0%	

p-value ≤ 0.05: statistically significant; *: significant; **: highly significant; Test applied: Fischer Exact

Table 20

Comparison of Occupation between Cases and Controls (n=178)

Occupation	Case (n=89)	Control (n=89)	Total	p-value
Retired	0 0.0%	4 4.5%	4 2.2%	**0.003***
Manual laborer	1 1.1%	0 0.0%	1 .6%	
Office worker	23 25.8%	34 38.2%	57 32.0%	
Student	0 0.0%	6 6.7%	6 3.4%	
House wife	51 57.3%	29 32.6%	80 44.9%	
Self employed	2 2.2%	0 0.0%	2 1.1%	
Field work	9 10.1%	12 13.5%	21 11.8%	
Other	3 3.4%	4 4.5%	7 3.9%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Fischer Exact

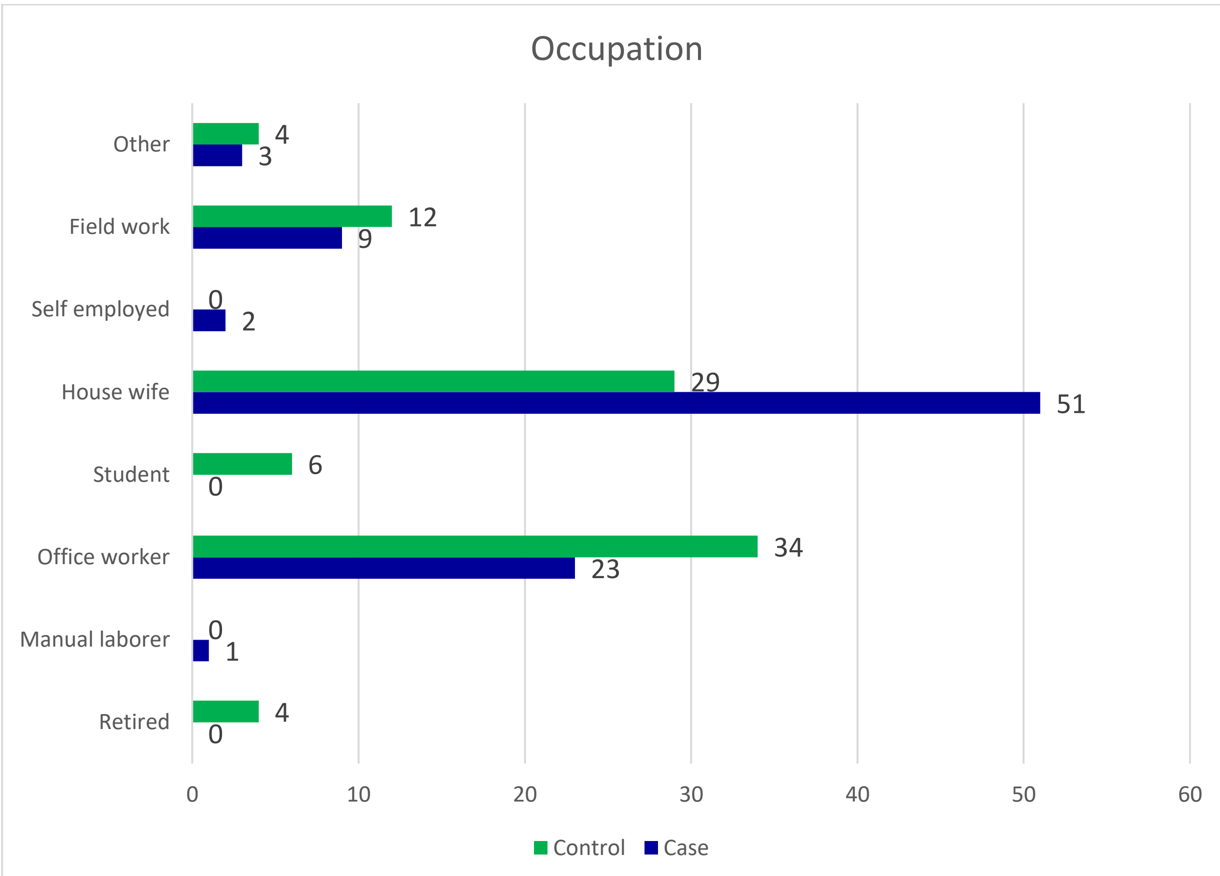


Fig 5. Bar Chart Demonstrating the Comparison of Occupation between Cases and Controls (n=178)

Table 21

Comparison of Physical Activity between Cases and Controls (n=178)

Do you exercise?	Case (n=89)	Control (n=89)	Total	p-value
Yes	17 19.1%	33 37.1%	50 28.1%	**0.008***
No	72 80.9%	56 62.9%	128 71.9%	
Total	89 100.0%	89 100.0%	178 100.0%	

p-value $\leq$ 0.05: statistically significant; *: significant; Test applied: Chi-square Test

Table 22

Comparison of Frequency of Exercise between Cases and Controls (n=178)

How often do you exercise?	Case (n=89)	Control (n=89)	Total	p-value
Daily	6 35.3%	20 60.6%	26 52.0%	0.193
2-3 times a week	7 41.2%	5 15.2%	12 24.0%	
Once a week	2 11.8%	5 15.2%	7 14.0%	
Once a month	2 11.8%	3 9.1%	5 10.0%	
Total	17 100.0%	33 100.0%	50 100.0%	

p-value ≤ 0.05: statistically significant; *: significant; Test applied: Fischer Exact Test

Table 23

Low Back Pain Related Responses in Cases (n=89)		
Duration of Pain	Number	Percent
< 1 year	50	56.2
1-2 years	19	21.3
3-4 years	7	7.9
>4 years	13	14.6
Frequency of back pain	Number	Percent
All the time	42	47.2
2-3 times during the day	19	21.3
Once a day	8	9.0
Occasionally	4	4.5
Constantly	1	1.1
Early morning	2	2.2
Off and on	12	13.5
All the time	1	1.1
Has the pain disrupted daily activities?	Number	Percent
Yes	80	89.9
No	9	10.1
Does pain disturb your sleep?	Number	Percent
Yes	28	31.5
No	61	68.5
Do you need to rest frequently due to back pain?	Number	Percent
Yes	86	96.6
No	3	3.4
Do you find it difficult to get up from a chair?	Number	Percent
Yes	44	49.4
No	42	47.2

Data presented as number and percentage

Table 24

Comparison of Back Pain Experience Amongst Cases (n=89)

When do you experience back pain?	Gender		Total	**p-value**
	Male	Female		
Physical activity	9 27.3%	24 42.9%	33 37.1%	**0.016***
Lifting weights	3 9.1%	0 0.0%	3 3.4%	
Bending	4 12.1%	9 16.1%	13 14.6%	
Praying	0 0.0%	1 1.8%	1 1.1%	
Walking	4 12.1%	3 5.4%	7 7.9%	
House work	0 0.0%	5 8.9%	5 5.6%	
Prolonged sitting	5 15.2%	3 5.4%	8 9.0%	
Prolonged standing	6 18.2%	4 7.1%	10 11.2%	
Bending, praying, walking	0 0.0%	5 8.9%	5 5.6%	
Sudden onset with no particular reason	2 6.1%	2 3.6%	4 4.5%	
Total	33 100.0%	56 100.0%	89 100.0%	

p-value ≤ 0.05: statistically significant; *: significant; Test Applied: Fischer Exact Test

Table 25

Relationship between Sacral Hiatal Parameters and Low Back Pain (n=89)

Shape of Hiatus	**O.R**	**C.I (95%)**	**p-value**
Inverted U	1.621	*0.432 - 6.086*	0.474
Inverted V	.556	*0.147 - 2.106*	0.387
M shape	2.000	*0.244 - 16.362*	0.518
Dumbbell	1.000	*0.173 - 5.772*	0.999
Bifid	1.000	*0.132 - 7.570*	0.999
Irregular	1		
Level of Apex			
1st sacral vertebra	2.5	*0.194 - 32.194*	0.482
2nd sacral vertebra	1.713	*0.460 - 6.372*	0.422
3rd sacral vertebra	0.551	*0.158 - 0.920*	0.35
4th sacral vertebra	1		
Level of Base			
3rd sacral vertebra	1.33	*0.113 - 15.704*	0.819
4th sacral vertebra	1.2	*0.155 - 9.301*	0.861
5th sacral vertebra	0.92	*0.126 - 6.755*	0.936
coccyx	1		

p-value ≤ 0.05: statistically significant; *: significant; Test Applied: Binary Logistic Regression Analysis

Table 26

Relationship between Sacral Hiatal Parameters and Low Back Pain

Variables	Group	O.R	C.I (95%)	p-value
Length of Hiatus (mm)	Control	1	*1.047 - 1.128*	**0.000** **
	Case	1.087		
Transverse Width (mm)	Control	1	*0.931 - 1.354*	0.224
	Case	1.123		
AP Diameter (mm)	Control	1	*1.025 - 1.204*	**0.01***
	Case	1.11		

p-value ≤ 0.05: statistically significant; *: significant; **: highly significant; Test Applied: Binary Logistic Regression Analysis in case and controls

CHAPTER 5

DISCUSSION

The current study investigated the incidence and relation of non-specific low backache with variations in anatomical parameters of the sacral hiatus, sociodemographic factors and level of physical activity. The observations of the study were compared between the patients of low backache and asymptomatic individuals.

In the current study the anatomical parameters of the sacral hiatus were divided into two groups: non-metric and metric parameters similar to studies conducted by Bagheri et al., (2017) and Singh, Singh, & Devi, (2017). In this study the shape, level of apex and level of base were included in the non-metric while the length, depth and width were part of the metric parameters. These were observed on radiographic images of the lumbosacral spine. A similar approach was used in the studies by Elumalai et al., (2016) and Saha et al., (2016).

In the current study the sacral hiatus was identified on the anteroposterior view of radiographic images of the lumbosacral spine. The sacral hiatus was localized at the inferior end of the 'sacral canal' as a radiotransparent area as described by Macchi et al., (2011). The margins of the articular processes lateral to the hiatal opening were used to identify the different hiatal shapes.

In the current study comparison of hiatal shape between the cases and control groups revealed higher incidence of the inverted 'U' (52.8%) as compared to the inverted 'V' (50.6%) in the groups respectively. In addition four variants of the hiatal shape (dumbbell, irregular, bifid and 'M') were observed in both groups in our study with varying incidences. We found no defects in the dorsal wall or absent sacral hiatus. In agreement with our findings high incidence of inverted 'V' shaped hiatus was observed in dry human sacra by Nasr, Ali, & ElSawy, (2014) (38.66%) and Osunwoke, Oladipo, Allison, & Orlu, (2014) (33.1%). Furthermore Elumalai et al., (2016) and Bhadra & Saha, (2017) also reported high incidence of inverted 'U' shapes in the cases. Similar incidences of hiatal shape variants to our study were observed by Bagheri et al., (2017), David, (2019) and Ukoha et al., (2014). In contrast to the current study, Deepa & Rajasekar, (2014) did not document 'M' shape among the hiatal variants and Elumalai et al., (2016) reported no dumbbell, irregular, bifid or 'M' shapes in the control group.

In the current study a statistically significant difference in the shapes of the sacral hiatus between the cases and controls was detected from which we can infer that the inverted 'U' and 'V' shapes are most common in both groups and variations occur due to genetic, racial and regional differences. In turn these variations predispose to the development of low back pain possibly due to compression of the spinal nerves by bony projections or reduction in the area of attachment of the muscles of the back. Similar findings were reported by Ali et al., (2014) who attributed the variations to the racial and regional differences. In addition Elumalai et al., (2016) also detected a significant difference in the hiatal shapes between the cases and control groups inferring that anatomical variations decrease surface area for attachment of back muscles and cause low back pain. Furthermore Ukoha et al., (2014) reported that variations of hiatal shape are related to the hiatal length. Saluja et al., (2019) reported importance of the irregular shaped hiatus in causing obstruction during caudal epidural block.

In the current study the apex of the sacral hiatus was identified at the lower end of the median sacral crest. Its level was described with reference to sacral vertebrae similar to the study conducted by Bagheri et al., (2017). The anteroposterior radiographic images of the lumbosacral spine were utilized for the comparison as done by Baske & Mondal, (2019).

We observed the hiatal apex most commonly at the level of S3 and S2 in both groups. The incidence of apex at S3 (73%) was higher and S2 (20.2%) was lower in the control group as compared to the cases (S3: 48.3%; 2: 41.6%). We also noticed higher frequency of apex at S1 (3.4%) in the cases as compared to controls (1.1%). Elumalai et al., (2016) reported similar findings in the cases as our study (S3: 52%; S2: 34%) however in contrast to our study in the control group, the apex was reported most commonly at S4 (88%) with lower incidence at S3 (12%). This difference of observations may be due regional or intra-observer variations when using radiographic images. In agreement with our findings in the control group dry human sacral studies by Ramamurthi & Reddy, (2013) and Singh et al., (2017) observed high incidence of hiatal apex at S3 (41.3%; 42.9%).

In our study the difference in level of apex between cases and controls was statistically significant. This indicates that the level of apex is dependent on the fusion of the lamina during development, a high level of apex increases the chances of low back pain due to elongated opening of the hiatus and exposure of the spinal nerves with reduced area for muscle attachment on the sacrum. Furthermore apex at level above S3 exposes the contents of the sacral canal and increases risk of iatrogenic injury. The outcomes of this study are in agreement with Elumalai et al., (2016) who reported an increased incidence of low back pain in cases with high apex and deficient dorsal wall. Baske & Mondal, (2019) also reported significance of the apex in relation to the length of the hiatus.

In the present study the base of the hiatus was identified as the area between the sacral cornua. It was described with reference to the level of the sacral vertebra. In this study the level of the base was compared between the cases and control groups as done by Elumalai et al., (2016).

In the current study the level of the base of the sacral hiatus extended from S3-1st coccygeal vertebra in both groups. It was observed at S5 most commonly in the cases (66.3%) and controls (71.9%). Other levels in order of frequency in both groups were S4, S3 and coccyx. In agreement with our findings among the controls, morphometric studies conducted by Dhuria, Dave, Ahuja, & Rustagi, (2018), Shanmugam & Puthuraj, (2017) and Nasr et al, (2014) reported high incidence of hiatal base at S5. In contrast to our observations in the cases Elumalai et al., (2016) reported higher incidence of base at the level of S4 (53%) rather than S5 (32%). This difference could be attributed to regional, assessment method and observer variations.

Our study revealed no significant difference in the level of base between the cases and controls. The findings of our study indicate that the level of the base of the hiatus does not influence the contents of the sacral canal and therefore it may be useful in cases where the apex cannot be identified on palpation or is high lying. In agreement with our observations Bagheri et al., (2017) advised the alternate use of the hiatal base for caudal procedures because it is located farther from the termination of the dural sac. Baske & Mondal, (2019) and Ukoha et al., (2014) also reported similar findings to our study. Significance between level of base and low back pain was not reported in other studies.

We determined the length of the hiatus using the observations of the apex and base. The length was measured by drawing a straight line from the midpoint of the base to the apex using Synapse software. In this study the measurements of the length were compared between the cases and control groups similar to the study by Elumalai et al., (2016).

In our study the mean length of the hiatus among the cases (30.09±10.02mm) was longer as compared to the control group (23.58±7.57mm). Similar findings to observations among our control group were documented by Pal, Ashfaqur Rahman, & Fatema, (2012) and Vedapriya et al., (2013) with lengths of 23.61± 8.28mm and 24.80± 9.45mm respectively. Bharathi, Janaki, & Veenatai, (2016) observed almost identical hiatal lengths (30.8mm) to our cases in unknown dry human sacra. In contradiction to our findings Baske & Mondal, (2019) reported shorter mean hiatal length among the cases (17.54±4.25 mm) and controls (15.11±3.69mm). We can deduce that the difference is because of the demographics of the study population and observer variations.

Our study revealed a high statistically significant difference in hiatal length between the cases and controls. We can assume that a long hiatus can contribute to the symptoms of mechanical low back due to its association with the dorsal surface of the sacrum and its muscular attachments. In addition hiatal length should be considered prior to interventions of the caudal region to prevent unnecessary complications. Similar observations were documented by Baske & Mondal, (2019) and Mondal & Baske, (2017) who reported longer lengths of the hiatus in cases as compared to controls.

To measure the 'anteroposterior diameter of the sacral hiatus' we used the lateral view of the lumbosacral spine radiographs. We measured the 'depth of the hiatus' at its apex as described by Nasr et al., (2014). The observations of the anteroposterior diameter were compared between the cases and control groups to determine significance of difference.

In our study the average depth of the hiatus in the cases and control groups was 3.38± 2.05mm and 3.06±1.28mm respectively. Similar finding was recorded by Manisha, Mrithunjay & Sinha, (2014) with mean anteroposterior diameter of 3.1±6mm. In contradiction to our findings morphometric study of dry human sacra by William, Jaiswal, Gupta, Koser, & Rathore, (2017) reported smaller depth of sacral hiatus (0.5± 0.118mm) while Kim et al., (2016) documented larger mean depth (6.8±2.5 mm). We believe these differences in observations are related to the mode of measurement, regional and observer variations.

In the current study no significant difference was found in depth of hiatus between cases and controls. Therefore it is evident that depths less than 3 mm could cause symptoms of low back pain. The depth observed in our study is adequate for caudal procedures. Similar findings were reported by Elumalai et al., (2016). Kilicaslan et al., (2015) documented anteroposterior diameter of less than 2 mm in 5% of low back pain cases. Significance of the differences of hiatal depth between cases and controls remains to be seen. Evidence of an association between the depth of the sacral hiatus and success rates of clinical procedures such as caudal epidural anesthesia has been investigated. Kim et al., (2016) reported significant association between the hiatal depths in failed caudal epidural block cases concluding that depth less than 2mm hinders needle advancement.

The transverse diameter was ascertained by identification of the sacral cornua and measurement of the intercornual distance from the edge of one cornu to the other. Similar method of estimation was used by Bhadra & Saha, (2017). The observations were compared between the cases and control groups to determine significance of difference. Similar approach was adopted by Baske & Mondal, (2019).

In the current study the hiatus was wider in the cases (13.34± 4.33mm) as compared to the control group (11.76± 3.51mm). Similar measurements as our control group were reported by Nasr et al., (2014) (11.50±3.13mm) and Singh et al., (2017) (11.59±3.25mm). In contrast to our observations smaller width was reported by Mondal & Baske, (2017) in the cases (10.27± 2.66mm) and controls (8.41±2.16mm). These differences could be due to the difference of measurement technique. Intercornual distance has been measured from the tip of the sacral cornua in some studies while in others the inner border of the cornua was used. In the current study there was significant difference in the transverse width between cases and controls. We can infer that this difference is due to developmental, racial, and demographic factors. In agreement with our study Baske & Mondal, (2019) and Mondal & Baske, (2017) reported significant differences between the two groups.

In the current study the non-metric (shape, level of apex, and level of base) and metric parameters (length, depth and width) were compared within the male and female cases to determine the significance of difference. Similar approach was adopted by Baske & Mondal, (2019) and Mondal & Baske, (2017).

In the current study the inverted ‘U’ and ‘V’ shapes were most common in both male and female cases. However a higher incidence of inverted ‘U’ shape was observed in the female cases (58.9%) and inverted ‘V’ (39.4%) and irregular (9.1%) shapes in the male cases. Similar findings were reported by Bhadra & Saha, (2017). In contrast to our study Kumar et al., (2009) observed higher incidence of inverted ‘U’ shape in the male cases and inverted ‘V’ in the female cases.

We found no statistically significant difference in the incidence of hiatal shapes between male and female cases. From the findings it is evident that the inverted ‘U’ and ‘V’ shapes are most common in both genders and the differences that we observed may be attributed to genetic factors or variations in sacral morphology. Similar findings were reported by Ahm, Ara, Ashrafuzzaman, Khatun, & Islam, (2014). After extensive literature search we found no studies reporting significant findings.

The apex of the hiatus in the male and female cases was most commonly observed at S3 and S2 with varying incidences. In the female cases we observed higher incidence of hiatal apex at S2 (46.4%) as compared to male cases in which it was at S3 (54.5%). Similar findings were reported by Bhadra & Saha, (2017). In contrast to our study Kumar et al., (2009) observed the apex at S4 in both male and female cases.

We found no significant difference in the level of apex of the hiatus between male and female cases. Similar findings were reported by Baske & Mondal, (2019) and Mondal & Baske, (2017). We can assume that the variations observed are attributed to morphological and development variations. Furthermore our findings indicate a high lying apex in females which may contribute to difficulties in clinical procedures (obstetric).

The base of the hiatus in the male and female cases in our study was most commonly observed at S5 (male: 60.6%; female: 69.6%) and S4 (male: 30.3%; female: 25%) with minor variation in incidences. Similar findings were documented by Baske & Mondal, (2019) and Mondal & Baske, (2017). Case control studies with contradictory findings were not detected after extended literature search.

According to our observations there was no statistically significant difference between the male and female cases with respect to the level of the hiatal base. Baske & Mondal, (2017) and Mondal & Baske, (2017) reported findings in agreement with our study. We believe that the variations observed are because of individual and genetic factors and do not pose a risk for low back pain or complications of caudal procedures.

In the current study the mean hiatal length was more in male cases (33.5mm±9.74mm) as compared to female cases (29.94±10.26mm). Baske & Mondal, (2019) and Mondal & Baske, (2017) also reported longer hiatus in males as compared to females however in comparison to our study the hiatal lengths were smaller (male:17.10±3.82mm; female:15.66±4.33mm). We can assume that this difference in the measurements between the studies may be due to racial, regional, and observer related factors.

In the current study we found no statistically significant difference in the hiatal length between male and female cases. Baske & Mondal, (2019) and Mondal & Baske, (2019) reported similar findings. We believe that the difference in hiatal lengths in the male and female cases could be an influence on the individual's experience of low back pain and should be considered prior to caudal approach in the clinical setting. No case control studies with significant findings were found. Among cross-sectional studies Ahm et al., (2014) and Yilmaz, Tokpinar, Acer, & Doğan, (2019) reported a significant difference in hiatal length between the genders which could be due to "methodological, dietary, socioeconomic, racial and genetic factors".

In the current study the average depth of the hiatus was smaller (3.21± 1.18mm) in the male cases as compared to the female cases (3.47± 2.42mm). In contrast to our findings Gokcek & Kaydu, (2018) observed higher values of hiatal depth in male (4.49±0.75mm) as compared to the female (4.45±0.88mm) low back pain patients. Also measurements were larger than our observations. The reason for higher values could be ethnic and methodological differences. We detected no significant difference in hiatal depth between the male and female cases. Similar results were documented by Gokcek & Kaydu, (2018).

The average transverse width in the male cases (13.63±4.38mm) was larger as comparted to the female cases (13.17±4.33mm). Similar observations were reported by Baske & Mondal, (2019) and Mondal & Baske, (2017) however the measurements in male (9.50±2.59mm) and female (9.09±2.29mm) cases of the studies were significantly smaller than our study. The width observed in our female cases was also more than both groups in the studies. Gokcek & Kaydu, (2018) (male: 16.6±2.04mm; female: 15.8±2.1mm) and Park et al., (2015) (male: 17.7±2.7mm; female: 16.5±2.7mm) also reported larger hiatal widths in male than female cases in similarity with our study. In contrast to our study Gokcek & Kaydu, (2018) and Park et al., (2015) had wider diameters. The reason for the differences in observations could be variations in individual physical structure, genetic makeup and ethnicity.

In our study the difference of width between the male and female cases was not statistically significant. Similar findings were reported by Baske & Mondal, (2019) and Mondal & Baske, (2017). Gokcek & Kaydu, (2018) and Park et al., (2015) reported significantly larger intercornual distance in male cases. The differences in results could be related to methodological reasons.

In the present study the incidence of the hiatal parameters in the cases were compared between the age groups. For this purpose the cases were divided into five categories (18-25, 26-35, 36-45, 46-55, and 56-65 years). Similar approach was also used by Baske & Mondal, (2019) and Mondal & Baske, (2017).

In the current study the inverted 'U' and inverted 'V' shapes were most commonly observed in ages 18-65 years. There was no significant difference of hiatal shape between the age groups. There were no previous case-control studies documenting the hiatal shape in the age groups. We can infer inverted 'U' and 'V' are considered normal for all ages.

In the current study the level of apex of the hiatus of low back pain cases between the ages of 18-65 years was found at the level of S3 and S2. Baske & Mondal, (2019) and Mondal & Baske, (2017) documented apex above S4 in majority of cases (88%) between the ages of 20 to 40 and above. From the findings we can deduce that low back pain may occur in individuals in all age groups and most commonly in people with apex above S4.

The base of the hiatus was most commonly visualized at the level of S5 and S4 in ages 18-65 years. Variable incidence of base at S3 and coccyx was observed in the ages 26-35, 36-45 and 56-65 years. In agreement with this study, Baske & Mondal, (2019) and Mondal & Baske, (2017) reported the base of the hiatus in majority of the cases (94%) at S5. We found no significant difference of hiatal base level in the age groups. We can deduce that a base level at S5 is most common with no predisposition towards low back pain. Any variations in morphometry would arise from ethnic and genetic differences.

The largest value of mean hiatal length was observed in the 36-45 (31.59$\pm$10.88mm), 46-55 (31.79$\pm$10.42mm) and 55-65 (30.43$\pm$4.06mm) year groups. The mean lengths in the ages

18-35 years were smaller (18-25: 23.15±3.53mm; 26-35: 29.45±10.68mm). In agreement with our study Baske & Mondal, (2019) reported similar hiatal lengths (30 years and below: 21-25mm in 12.50%; 31-40 years: >25mm in 5.26%; 40 years and above: >25mm in 3.33%). Kilicaslan et al., (2015) observed similar findings in the ages of 20-39 years however lengths in the older age group (60-80years) were smaller as compared to our observations. The reason behind these differences could be regional, hereditary and observational.

We found no statistically significant difference in hiatal lengths of the cases between the age groups. This indicates that age related changes are not responsible for anatomical variations of the hiatus. Developmental anomalies however may result in longer or shorter hiatal lengths. Similar findings were reported by Baske & Mondal, (2019), Kilicaslan et al., (2015) and Mondal & Baske, (2017).

The anteroposterior diameter of the hiatus was the largest (3.91±3.23mm) in the 36-45 followed by (3.26±1.21mm) 26-35 year groups. Smaller diameter was observed in the ages from 18-25 (2.98±1.23mm) and 56-65 years (2.76±1.09mm). In agreement with our study Kilicaslan et al., (2015) observed smaller depths in ages 60-80 years (males and females: 3.9±1.2mm) and larger depths in ages 20-39 years (males: 4.3±1.2mm; females: 4.4±1.2mm). However, the values recorded by Kilicaslan et al., (2015) in all age groups are larger than our study. The differences may be due to racial factors and mode of study.

We observed no significant differences in the hiatal depths across the age groups in the cases. The findings indicate that there is no relation of age with the variations of hiatal depth and low back pain. In our study population the depth of the hiatus is sufficient for safe caudal procedures. We suggest that reduction in depth should be anticipated especially in the elderly population where ossification of the sacrococcygeal membrane is more likely to occur. In contradiction to our study Kilicaslan et al., (2015) detected significant difference in hiatal depth with advancing age and deduced that age related changes may cause decrease in the hiatal depth.

In the current study the largest hiatal width was observed in the ages 36-45 (14.04±4.93mm) and 46-55 years (13.85±5.39mm) while the smallest width (10.41±3.04mm) was present in the 55-65 years group. Baske & Mondal, (2019) and Mondal & Baske, (2017) reported similar findings. Kilicaslan et al (2015) reported larger diameters in comparison to our study (20-39 years: 21±4.4mm (males) & 21.2±4.1mm (females); 40-59 years: 21.1±3.5mm (males) & 19.8±3.5mm (females); 60-80 years 20.5±5.1mm (males) and 20.2±3.3mm (females). These differences could be related to racial and regional variations.

We detected no significant difference in the diameter of the hiatus in cases between the age groups. We can deduce that variations of the width are not related to age and low back pain. Differences in observations between the studies can be attributed to measurement technique and regional factors. Baske & Mondal, (2019), Kilicaslan et al., (2015) and Mondal & Baske, (2017) reported similar findings.

In the current study the demographic data of the subjects (gender, marital status, occupation, height, weight, and BMI) was compared between cases and controls to detect significance of difference in relation to low back pain. A similar approach was adopted by Biglarian et al., (2012).

We observed high incidence of low back pain among the females (62.9%) as compared to the males (37.1%). Similar findings were reported by Husky et al., (2018) (women: 41.3%); men: 34.3%), Maher et al., (2017) and Shirazi et al., (2017) (women: 58.5%). In contradiction to our findings Zafar et al., (2018) found high prevalence of low back pain in men (51.7%) compared to women (48.3%). This difference could be because of high number of female participants in the study.

We found no significant difference in gender distribution among cases and control groups. We can assume that males and females are equally susceptible to develop low back pain. Similar findings were reported by Arslan et al., (2016), Baske & Mondal, (2019 and Mondal & Baske, (2017). In contradiction Furtado et al., (2014) reported significant difference in prevalence of low back pain in the female gender. This may be attributed to the combination of biological, psychological and social factors in the study group.

In our study a large number of cases belonged to the married (91%) as compared to unmarried (9.0%) group. In corroboration with our study Arslan et al., (2016) observed high point and lifetime prevalence of low back pain in married (33.9%; 77%) as compared to unmarried (20%; 54.1%). Similar findings were also reported by Ramdas & Jella, (2018) whereby 90.8% low back pain cases were married and 9.2% were unmarried. Contrary to our study El-Metwally et al., (2019) found higher incidence of back pain in the unmarried participants (60%) as compared to married (40%). The difference in observations could be due to variation in the demographics of the participants, social and cultural factors.

We detected significant difference between the cases and controls with reference to the marital status. We believe this is co-dependent on the cultural, biological, psychological and social factors. Similar observations were reported by Arslan et al., (2016) and Husky et al., (2018).

In the current study the highest numbers of cases (27; 30.3%) were observed in 36-45 years age group, followed by 26-35 years (25; 28.1%) and 46-55 (22; 24.7%) years. The smallest number of cases was observed in 18-25 (9; 10.1%) and 56-65 years groups (6; 6.7%). Similar findings were noted by Ramdas & Jella, (2018) in ages 31-40 (34; 34.6%) for males and 41-50 (45; 38.1%) for females. Zafar et al., (2018) also reported highest prevalence of back pain in ages 21-40 years (48%). In contrast to our findings Husky et al (2018) reported highest number of cases in ages 70-79 (47.1%). The difference could be because of regional, health related factors and larger age range of participants.

In the current study there was no statistically significant difference in the age groups of the cases and controls. Our observations indicate that low back pain may occur in any age group. We believe that combination of individual based factors such as lifestyle, mental and physical health are contributors. Furtado et al., (2014) also found no significant difference of age in the groups. In contradiction to our study Husky et al., (2018) found significant difference between cases and controls.

In our study the mean height in the controls (166.84±7.95cm) was insignificantly more in controls as compared to cases (164.64±7.95cm). Similar findings were recorded by Najafi, Rezasoltni, & Abedi (2018) (cases: 1.69±1 m; controls: 1.71±1m). Sribastav et al., (2018) reported smaller heights in the cases (160±12 cm) as compared to our study. The racial and regional variations could be the reason for the difference. From the findings we can infer that variation in height is not directly related to predisposition towards low back pain. Najafi et al., (2018) and Yun et al., (2012) reported similar findings.

In the current study mean weight in the cases (72.67±13.28 kg) was significantly higher than controls (62.65± 9.32kg). We believe that increase in the weight contributes to increased strain on the muscles of the back which with the combination of hiatal variations can cause low back pain. In similarity with our study Brady et al., (2016) observed significant differences in the mean weights of female cases (65.2±13.9kg) and controls (66.3±5.0kg). In contradiction to our study Najafi et al., (2018) recorded no significant differences in the weights between cases (72.9±9kg) and controls (75.3±11kg). This difference is because of small sample size and demographic variations.

In our study majority of the cases (41.6%) belonged to the overweight category whereas the control group had normal values in majority (86.5%). Also the cases had BMI in the obese class 1 (16.9%) and obese class III (3.4%) whereas smaller number of controls belonged to overweight category (6.7%). Similar findings were observed by Arslan et al., (2016) in the cases (obese group: 46.2%; non-obese group: 76.9%). Peng, Perez, & Gabriel (2018) also documented high prevalence of low back pain in the obese (36.4%) and overweight (29.6%) groups.

We found highly significant differences of BMI between the cases and control groups. This means that in individuals with high values of the body mass index the probability of low back pain increases due to the added stress on the extensor muscles of the back. Similar findings were reported by Arslan et al., (2016) and Furtado et al., (2014). On the contrary Najafi et al., (2018) documented no significant difference between the two groups. This could be attributed to the small sample size, demographic and biological factors of the participants.

In our study majority of the cases were housewives (44.9%), office workers (32%) and field workers (10.1%) as compared to the controls. The difference was highly significant. In agreement with our findings Husky et al., (2018) reported cases most commonly in home makers (43.2%) and farmers (46.4%). Zafar et al., (2018) also observed back pain most commonly in housewives (30%), followed by office workers (18.1%), private jobs (14.7%) and healthcare workers (12.3%). We can deduce that high incidence in the groups is related to posture, prolonged working hours in odd positions without back support and adequate rest.

In our study incidence of low back pain was higher in the non-exercising cases (80.09%) as compared to the controls (62.9%). The difference in the groups was statistically significant which indicates that with physical activity there is increase in muscle strength and blood flow which improves general health. Similar finding were reported by Arslan et al., (2016) (non-exercising: 37.1%; exercising group: 21.4%) and Zafar et al., (2018) (76.3%). Lionel

(2014) also observed a significant difference in cases and controls in relation to exercise. Contrary to our study, Furtado et al., (2014) detected no significant difference in the groups. This difference could be because of regional, cultural and demographic factors.

In the current study we observed higher incidence of back pain in cases (11.8%).) with less number of exercise sessions (monthly) as compared to controls (9.1%). In agreement with our study Arslan et al., (2016) observed high point prevalence of low back pain (38.9%) with minimum number of exercise sessions (once a week). Lionel (2014) reported that high number of cases exercised occasionally and rarely (32.7%; 20.3%) as compared to controls (13.3% & 2%).

The difference between the frequencies of exercise between the groups was not significant. We can assume that the type of activity rather the number of sessions holds value in maintenance of health and prevention of low back pain. Similar findings were reported by Olyaei et al., (2017) had similar findings to our study with no significant difference in point prevalence of low back pain. On the contrary Lionel (2014) observed significant difference between the groups. This difference could be due to the biological, lifestyle, and psychosocial factors.

In our study a large number of cases reported chronic low back pain within one year (50 cases; 56.2%) followed by complaints from 1-2 (19 cases; 21.3%), 3-4 (7 cases; 7.9%), and >4 years (13 cases; 14.6%). This highlights that the fact that majority of the participants have been suffering from chronic pain. We believe that this is related to the sociocultural beliefs and high individual tolerance towards pain. Ramdas & Jella, (2018) documented similar findings to our study with highest prevalence of cases within one year (64.6%). On the other hand the study by Koutenaei, Mosallanezhad, & Hosseinzadeh (2017) inducted only cases than occurred within one year. This could be because of methodological difference.

In the current study a high number of cases reported with pain that occurred all the time (47.2%), followed by 2-3 times during the day (21.3%), and off and on (13.5%). Other responses recorded in order of frequency were once a day (9%), occasionally (4.5%), early morning (2.2%) and constantly (1.1%). After thorough literature search to our knowledge, frequency of low back pain during the day has not been documented in other studies. Our findings indicate that the pain was related to muscle spasm and possibly posture related activity. The sociocultural beliefs and stress experience by the individual may have an impact on the frequency of pain.

In our study 89.9% of cases were not able to complete their daily tasks while 10.1% had no problems. We can infer that the pain was severe and debilitating in the majority of the cases and affected all aspects of their lives. Early reporting of symptoms would help to possibly reduce the complications, alleviate psychological and physical distresses. Similar findings were recorded by Hussain, Taufiq, & Taimoor-ul-Hassan (2017) in which 23.5% of cases had to take leave from work due to the back pain.

In our study sleep disturbance due to pain was recorded in 31.5% and no trouble with sleep was observed in 68.5% of cases. Sleep disorders in low back pain were also observed by Zafar et al., (2018) in 41.6% of cases. In our study 96.6% cases reported need for frequent rest due to the pain while 3.4% did not require rest. The observations indicate that the pain was severe enough to affect daily functioning. In addition we can infer that the experience and response of pain varies between individuals. Similar results were documented by Rathore et al., (2017) whereby 94% cases agreed that rest relieves back pain. In this study 49.4% experienced difficulty in getting up from a chair and 47.2% had no difficulty. Husky et al., (2018) observed physical functioning difficulties in 81.34% cases. These findings indicate that in our study a large number of cases had severe, intense pain with functional loss which can lead to depression and increase in economic burden because of the days taken off from work.

In the current study the aggravators of back pain among male and female cases were physical activity (37.1%), prolonged standing (11.2%), prolonged sitting (9%), walking (7.9%), house work and bending/praying/walking (5.6%), sudden onset with no particular reason (4.5%), lifting weights (3.4%) and praying (1.1%). In congruence with our findings Arslan et al., (2016) reported high prevalence of cases (51.2%) with prolonged sitting (>8 hours), standing (37.7%) and forward bending (36.4%). Zafar et al., (2018) also documented high incidence (50.4%) of cases with prolonged sitting, weight lifting (48.5%), and bending (41.6%).

In the current study the difference between the activities was statistically significant. We can deduce that with proper posture during daily activities, adequate rest, and healthy diet the complaints of back pain can be reduced and prevented. Furthermore an individually designed physical activity program should be incorporated in the routine. Aminuddin, Moin Uddin, Choudhury, & Guha, (2014) reported significant association between bending and twisting movements and back pain. Arslan et al., (2016) also reported significant differences with the prolonged sitting, standing time per day and forward bending.

In the current study the relationship between the variations of the sacral hiatus parameters and complaints of low back pain was determined. These assessments to our knowledge have not been investigated in prior studies.

In the current study analysis of the different hiatal shapes revealed a positive association between low back pain and the inverted ‘U’ (O.R=1.621; C.I: 0.432-6.086) and ‘M’ shapes (O.R=2; C.I: 0.244-16.362). Equal risk for low back pain was observed with the dumbbell (O.R= 1; C.I: 0.173-5.772) and bifid hiatal shapes (O.R=1; C.I: 0.132-7.570) shapes. No association between low back pain and the inverted ‘V’ shaped hiatus was found in our study (O.R=0.556; C.I: 0.147-2.106).

In the current study highest risk of low back pain was observed with hiatal apex at levels S1 (O.R=2.5; C.I: 0.194-32.194) and S2 (O.R= 1.713; C.I: 0.460-6.372). On the other hand no significant risk was determined with apex at level of S3 (O.R=0.551; C.I: 0.158-0.920). This proves our assumption that the variations of hiatal apex are associated with low back pain possibly due to reduced surface area for muscle attachment.

In the current study risk of low back pain was associated with base at levels S3 (O.R= 1.33; C.I: 0.113-15.704) and S4 (O.R=1.2; C.I: 0.155-9.301). Base levels at S5 revealed no significant risk of low back pain (O.R= 0.92; C.I: 0.126-6.755). This means that defect in the dorsal wall of the sacrum would affect the anatomical position of the base and in turn the attachment of surrounding structures.

In the current study an association between the length of the sacral hiatus (O.R=1.087; C.I: 1.047-1.128), transverse width (O.R=1.123; C.I: 0.931-1.354), anteroposterior diameters (O.R=1.11; C.I: 1.025-1.204) and risk of low back pain was observed. The differences in hiatal parameters between the cases and controls were statistically significant. Therefore we can infer that variations in the anatomical parameters of the hiatus are risk factors for nonspecific low back pain.

CHAPTER 6

CONCLUSION

The current study presented with the interesting fact that non-specific low back pain may occur in relation to variations of sacral hiatus anatomy in both genders. Hiatal variations are not age or gender dependent. There is a significant association between the variations of shape, apex, length, and anteroposterior diameter of the sacral hiatus with “low back pain”.

It was identified in the current research that the inverted ‘U’ and ‘M’ shaped sacral hiatus were positively related to “low back pain”. A hiatal apex at S1 or S2, base at S3, long hiatal length (more than 30mm), wide transverse diameter (more than 13mm) and variations in the anteroposterior diameter pose high risk of the condition.

There was predominance of the disease in the married and non-exercising individuals. High incidences of cases were found in house wives, office workers and field workers. The most common aggravators among cases were prolonged sitting, prolonged standing, house work (twisting movements of trunk), lifting weights, and bending among others. The frequency of the disease was associated with an increased weight and high BMI.

6.1 RECOMMENDATIONS

1. A longitudinal study should be conducted using a larger cohort.
2. Study should be conducted using an alternate imaging modality such as ultrasound, CT scan and MRI to evaluate the relationship between dimensions of sacral hiatus, dural sac, and incidence of low back pain.
3. Knowledge should be disseminated to clinicians so that the factors contributing to the disease are addressed and necessary precautions are during interventional procedures.
4. General population should be made aware of lifestyle modifications before the onset of the disease.

6.2 STRENGTHS OF STUDY

1. This study is pioneer study in Pakistan conducted in two different locations evaluating the parameters of sacral hiatus and their relation with frequency of 'non-specific low back pain'.
2. The study correlated the demographic and lifestyle factors with the incidence of the condition.
3. The findings of the study can be shared by the physicians with the patients and general population for lifestyle modifications to prevent disease incidence.

6.3 LIMITATIONS

1. The study used X-Ray images which can be distorted by artifacts (intestinal gas, fecal matter and full urinary bladder).
2. Only one form of assessment (X-ray) was used to document variations of sacral hiatus anatomy.
3. Other parameters of the hiatus were not measured because of imaging modality chosen.
4. Study sample size was small.
5. Study was conducted in a single city.

CHAPTER 7

7.1 REFERENCES

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7.2 APPENDICES

(A) BUMDC-FRC Approval Letter

FACULTY RESEARCH COMMITTEE
BAHRIA UNIVERSITY MEDICAL & DENTAL COLLEGE

Ref No: FRC-BUMDC -13/ 2019/Ana-002

Date: 9th October, 2019

To,
Dr. Samia Khalid Khokhar
M.Phil. Student
Department of Anatomy
BUMDC, Karachi

Subject: **APPROVAL OF SYNOPSIS**

The Faculty Research Committee has approved the synopsis of below mentioned Student.

Name of Student: Dr. Samia Khalid Khokhar

Title: **Incidence of Low Backache in relation to Anatomical Variations of Sacral Hiatus.**

Further this letter is recommended and referred to ERC for approval on Ethical grounds.

Regards
Assist Prof. Dr. Mehreen Lateef,
CO- CHAIRPERSON FRC-BUMDC

Cc:
Director General
Principal
FRC Record
PG Secretariat

Faculty Research Committee, Bahria University Medical College
Sailor's Street, Adjacent PNS-SHIFA DHA
Webmail: rrc-bumdc@bahria.edu.pk

(B) ERC Approval Letter

BAHRIA UNIVERSITY MEDICAL AND DENTAL COLLEGE

Defence phase II, Sailor Street, adjacent to PNS Shifa, Karachi. Tel: 021-35319491-9

ETHICAL REVIEW COMMITTEE

LETTER OF APPROVAL

Date: 09-Jan-2020

PATRON
Prof. Asad Ullah Khan
Principal & Dean
Health Sciences(BU)

CHAIRPERSON
Prof. Ambreen Usmani

SECRETARY
Dr. Quratul Ain Omaeer

MEMBERS
Prof M Alamgir
Prof Anis Jafarey
Ms Nighat Huda
Surg Cdre Amir Ejaz
Prof Reza H Syed
Ms Shabina Arif
Mr M Amir Sultan
Surg Lt Cdr Farah
Surg Lt Cdr Sadia
Dr. Ambreen Surti

Dr. Samia Khalid Khokhar
M. Phil Student
Department of Anatomy
BUMDC-Karachi

Subject: Institutional Approval of research study

Title of Study: " Incidence of Low Backache in Relation of Anatomical Variations of Sacral Haitus"

Principal Investigator: Dr. Samia Khalid Khokhar, M. Phil Student Department of Anatomy, Bahria University Medical and Dental College.

Reference No: ERC 03/2020

Dear Dr. Samia Khalid Khokhar

Thank you for submitting the above mentioned study proposal. ERC Bahria University Medical and Dental College has reviewed this project in the meeting held on 1st- Jan -2020 and gives approval. Kindly notify us when the research is complete.

Regards,

16/1/2020

DR. QURATUL AIN OMAEER
Secretary ERC
BUMDC

PROF DR AMBREEN USMANI
Chairperson
BUMDC

Cc:
DG-BUMDC
Principal BUMDC
Chairperson ERC

ADVANCED RADIOLOGY CLINIC (Pvt.) Ltd.

June 01, 2020

Name of Principal Investigator : DR. SAMIA KHALID KHOKAR, M. Phil Student Anatomy, Bahria University Medical and Dental College.

Co-Investigator : Prof. Dr. Aisha Qamar, Professor Anatomy, Bahria University Medical and Dental College.

Title: "Incidence of Low backache In Relation to Anatomical Variations of Sacral Hiatus."

Documents Reviewed:

1. Study Proposal
2. Questionnaire
3. Informed consent

The study proposal has been approved for data collection from Advanced Radiology Clinic Pvt Ltd after review of proposal and answers to ethical concerns.

Advanced Radiology Clinic (Pvt) Ltd

Dr. Ahmed Swaleh
Radiologist

Behind Taj Medical Complex, Off. M.A. Jinnah Road, Karachi-74400, Phones: 3278-3535, 3278-3536, 3278-6373, 3278-6500
Fax: 3278-8200 UAN: 111-111-272 E-mail: arcra@cyber.net.pk Website: www.arcpl.com

(C) Consent Form (English)

WRITTEN INFORMED CONSENT FORM OF PARTICIPANT

I am giving my consent to participate voluntarily and at my own will in the research project that aims for prevention and early diagnosis of low back pain. The project will evaluate parameters for early diagnosis of variations of sacral hiatus in the subjects with low back pain.

I have been explained in detail the nature and significance of participating in the project and I understand the provided explanation.

I have been told that findings of my disease and my data will be kept strictly confidential and will be used only for the benefit of community, publications and paper presentations.

I have been explained that laboratory investigations will be conducted to evaluate my health status and to diagnose and monitor my disease process. For this purpose I fully agree to give film of X-ray pelvis to the researcher.

I also agree to give all relevant information needed, in full and to the best of my knowledge to the researcher. It is clarified to me that no incentive, financial assistance or reimbursement will be provided to me for participating in the study whereas I do have the right to withdraw from the study at any time.

I am advised to contact Dr. Samia Khalid on mobile number: 0334-2367634 or visit Bahria University Medical and Dental College in case of query related to my disease.

Name of Participant: ____________________S/o, D/o, W/o_____________

Signature of Participant:_________________

Name of Researcher:_______________________________________

Signature of Researcher:____________________________

Date:_______________

(C) Consent Form (Urdu)

<u>شرکاء کے لئےتحریری رضا مندی فارم</u>

میں رضا کارانہ طور پر اس تحقیق میں حصہ لینے کےلیے اپنی رضا مندی دے رہا/ رہی ہوں۔ اس منصوبے میں جس کا مقصد پیٹھ کے نتیجے کے درد کی روک تھام اور ابتدائی تشخیص ہے۔ اس منصوبے میں Sacral Hiatus کے مختلف حالتوں کے ابتدائی تشخیص کے لیے پیرا میٹرز کا اندازہ کریں گے ان لوگوں میں جو پیٹھ کے درد کا شکار ہیں۔

مجھے اس منصوبے میں حصہ لینے کےبارے میں اور اہمیت کے بارے میں تفصیل سے بیان کیا گیاہے۔ اور میں فراہم شدہ وضاحت سمجھتا /سمجھتی ہوں۔ مجھے بتایا گیا ہے کہ میری بیماری کے نتائج اور میرے انداز و شمار کو سختی سے خفیہ رکھا جائے گا۔ اور صرف کمیونٹی ، پبلکیشن اور پےپر پریسنتیشن کیلئے استعمال کیا جائے گا۔

مجھے وضاحت کی گئی ہے کہ میری صحت کا اندازہ کرنے اور میری بیماری کی تشخیص اور نگرانی کرنے کیلئے لیبارٹری کی تحقیقات کی جائیں گی۔اس مقصد کیلئے میں نے مکمل طور پر ایکسرےL spine فلم، محقق کو دینے کیلئے اتفاق کیا۔ میں اس سے بھی اتفاق کرتا/کر تی ہوں کہ تمام متعلقہ ضروری معلومات جو بہتر طورسے میرے علم میں ہے محققین کو دوں گا/گی۔ یہ مجھے واضح ہے کہ محققین کی طرف سے لیب کی تحقیقات کی لاگت کے علاوہ اس مطالعہ میں حصہ لینے کیلئے مجھے کوئی بھی رقم فراہم نہیں کی جائے گی۔ جبکہ مجھے کسی بھی وقت مطالعہ سےنکلنے کا حق ہے۔

مجھے مشورہ دیا گیا ہے کہ ڈاکٹرسمعیہ خالد سے موبائل نمبر : 03342367634 پریا بحریہ یونیورسٹی میڈیکل اور ڈینٹل کالج سے میری بیماری سے متعلق کسی بھی سوال کے معاملے میں رابطہ کرنے کا۔

شریک/ مریض کا نام:____

شریک/ مریض کے دستخط:______________________________________

محقق کا نام:____

محقق کے دستخط:____

(D) Subject Evaluation Proforma

SUBJECT EVALUATION FORM

A.

Name:	**Patient Id:**	**Date:**	**Age:**
Gender: ○ **Male** ○ **Female**	**Marital Status:** ○ **Married** ○ **Single**	**Height (cm):**	**Weight (kg):**
BMI:	**Contact Number:**		
Occupation: ○ **Retired** ○ **Manual laborer** ○ **Office worker** ○ **Student** ○ **House wife** ○ **Self employed**			

1. Has Low Back Pain: [Yes] [No]

<u>If Yes:</u>

1.1 How long have you had back pain? ____________________________

1.2 Frequency of Back Pain: ___________________________

1.3 Has the pain disrupted daily activities: [Yes] [No]

1.4 Does the pain disturb your sleep? [Yes] [No]

1.5 Do you need to rest frequently due to back pain? [Yes] [No]

1.6 When do you experience back pain? ____

1.7 Do you find it difficult to get up from a chair? [Yes] [No]

1.8 Do you use back care equipment? [Yes] [No]

1.9 Do you exercise? [Yes] [No]

2. <u>If Yes:</u>

2.1 How often do you exercise? [Daily] [2-3 times a Week] [Once a week] [Once a month]

B.

Radiographic observations of Sacral Hiatus:

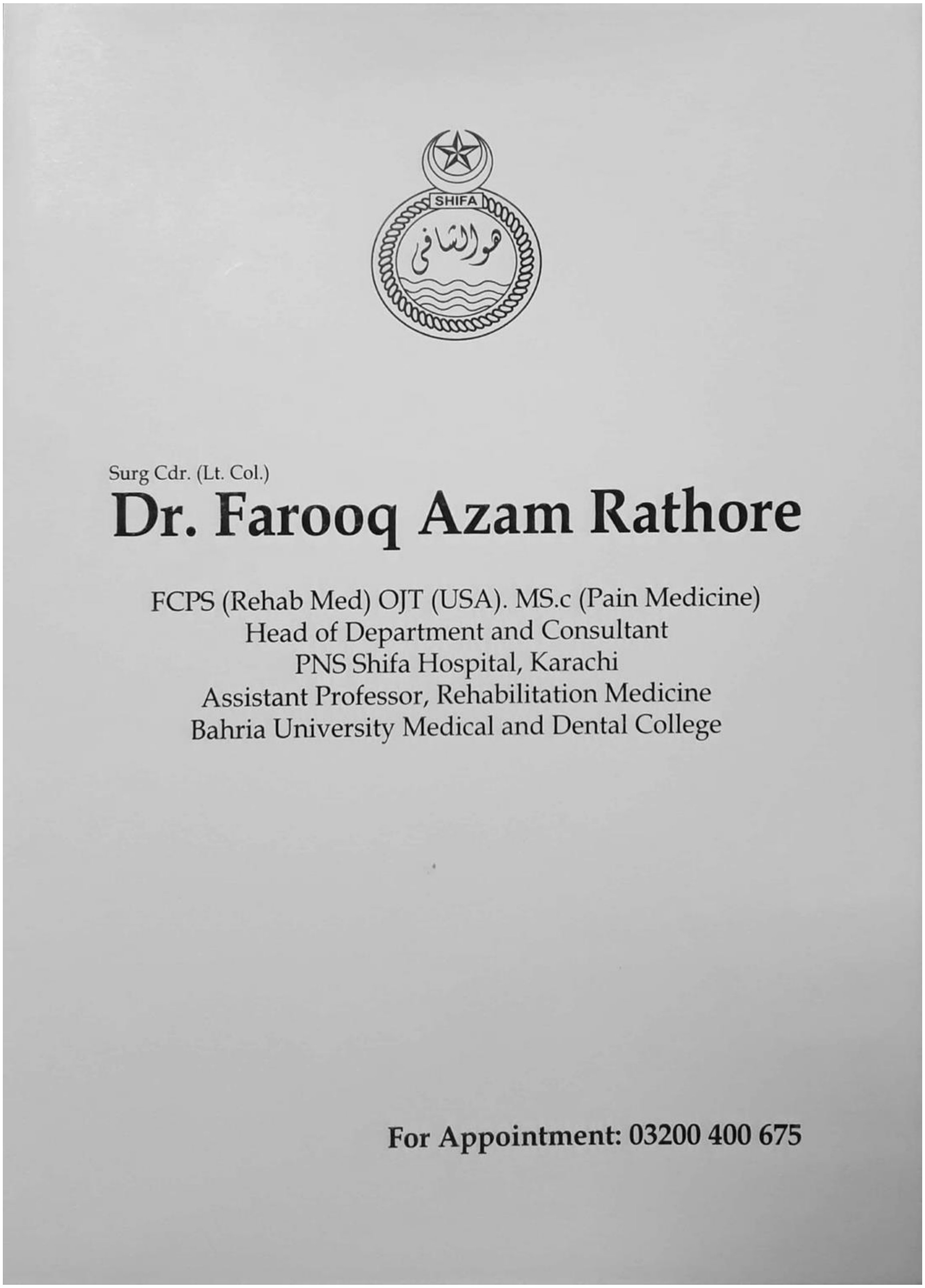
1. Shape	**Inverted U**	**Inverted V**	**Bifid**	**Irregular**	**Dumbbell**	**M**
2. Level of Apex	**1^{st} Sacral Vertebra**	**2^{nd} Sacral Vertebra**	**3^{rd} Sacral Vertebra**		**4^{th} Sacral Vertebra**	**5^{th} Sacral Vertebra**
3. Level of Base	**2^{nd} sacral vertebra**	**3^{rd} sacral vertebra**	**4^{th} sacral vertebra**		**5^{th} Sacral Vertebra**	**Coccyx**
Absent Dorsal Wall (Sacral Hiatus not seen)						

4. Length (mm): ______________________________

5. Antero-Posterior diameter (mm): ________________

6. Transverse width (mm) ________________________

(E) Hospital Card


SHIFA

هوالشافی

Surg Cdr. (Lt. Col.)

Dr. Farooq Azam Rathore

FCPS (Rehab Med) OJT (USA). MS.c (Pain Medicine)
Head of Department and Consultant
PNS Shifa Hospital, Karachi
Assistant Professor, Rehabilitation Medicine
Bahria University Medical and Dental College

For Appointment: 03200 400 675

(F) Turnitin Plagiarism Check Report

Thesis

ORIGINALITY REPORT

11%	4%	7%	7%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to University of Birmingham Student Paper	1%
2	Submitted to University of Sydney Student Paper	<1%
3	Rubi Saikia, Mukul Sarma. "VARIATIONS OF SACRAL HIATUS IN DRY HUMAN SACRA: AN ANATOMICAL STUDY", Journal of Evidence Based Medicine and Healthcare, 2016 Publication	<1%
4	worldwidescience.org Internet Source	<1%
5	Submitted to Georgia Southern University Student Paper	<1%
6	Submitted to Cardiff University Student Paper	<1%
7	"Advances in Minimally Invasive Surgery and Therapy for Spine and Nerves", Springer Science and Business Media LLC, 2011 Publication	<1%