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ABSTRACT

Background: The gold standard for hernia repair has remained a tension free, permanent, simple to perform and safe repair. The absolute achievement of this has remained elusive. For a long time, the Mesh hernioplasty was considered the closest to this standard and was adopted by the European Hernia Society as the procedure of choice. The prosthetic Mesh, mostly poly-propylene mesh, has many inherent drawbacks. It is costly, mostly non-available in poor countries, carries the risk of mesh displacement and hernia repair failure, and is associated with high risk of mesh infection that will require subsequent removal. The Desarda No-mesh, biological tissue repair obviates the noted drawbacks associated with the mesh, and in addition, provides a strong, mobile and physiologically dynamic posterior inguinal wall that effectively limits repair failure. This can be a good alternative to the Modified Bassini Repair that is fraught with high recurrence.

Objectives: To compare the short and medium term outcomes between the Modified Bassini and the No-mesh Desarda hernia repair.

Keywords: randomised trial, desarda repair, modified bassini repair.

Classification: DDC Code: 617.559059 LCC Code: RD621

Language: English

London Journals Press

LJP Copyright ID: 392823

London Journal of Medical and Health Research

Volume 22 | Issue 2 | Compilation 1.0

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It is costly, mostly non-available in poor countries, carries the risk of mesh displacement and hernia repair failure, and is associated with high risk of mesh infection that will require subsequent removal. The Desarda No-mesh, biological tissue repair obviates the noted drawbacks associated with the mesh, and in addition, provides a strong, mobile and physiologically dynamic posterior inguinal wall that effectively limits repair failure. This can be a good alternative to the Modified Bassini Repair that is fraught with high recurrence.

Objectives: To compare the short and medium term outcomes between the Modified Bassini and the No-mesh Desarda hernia repair.

Methods: A total of 50 adult male and female patients with primary inguinal hernias were randomly allocated intraoperatively to undergo Desarda No-mesh or Modified Bassini inguinal hernia repair. Each patient is allocated to either of the procedures through balloting.

Results: From our evaluation of the short-term and medium-term outcomes, such as surgery duration, immediate post-operative pain, ability to achieve normal gait, early return to work and early recurrence; Desarda technique is effective and safe, with the least post-operative complications compared to Modified Bassini Inguinal Hernia repair.

Conclusion: Desarda repair is easy to perform and has been shown to take shorter operative time. Also, it is associated with less post-operative pain and there is no need of mesh. It is therefore cost effective and is similar to Lichtenstein method in terms of early recurrence rate. Desarda hernia repair can be a good substitute to Lichtenstein repair and should be recommended for younger patients because of the proposed lesser risk for post-operative sexual dysfunction and subfertility.

Keywords: randomised trial, desarda repair, modified bassini repair.

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I. INTRODUCTION

A hernia is an abnormal protrusion of a viscus or a part of it, through an opening or weak point in the wall of the cavity containing the viscus. Hernia, especially Inguinal Hernia, is a common presentation at the General Surgery Unit. The life time risk of developing a hernia is 10% for all populations, 94% of all hernias are found in the groin region and 95% of male hernias are inguinal, while 9% of female hernias are femoral

[1]. The estimated life time risk for developing Inguinal hernia is 27% for the male and 3% for the female [2]. The inguinal hernia is refuted to be the most common type in Africa [3]. Surgical repair of an inguinal hernia is the most effective treatment for this disease, but, it is inherently associated with many problems, amongst which are; post-operative pain and recurrence [4]. The ideal surgical repair should be easy to perform, tension free, secure, safe and cost effective [5]. The Desarda No-mesh repair is said to have met these criteria and is even slightly superior to Lichtenstein hernia repair [6], the gold standard repair adopted by the European Hernia Society [7].

The Lichtenstein Mesh hernioplasty is not free of many drawbacks despite being the gold standard. It is very costly, especially for the poor rural patient in Africa, mostly unavailable, except in big cities. It is also associated with Mesh migration or displacement and troubling Mesh related surgical site infection that may necessitate its removal [8].

It is also said to be associated with higher incidence of post-operative pain, feeling of foreign body sensation and mesh related sexual dysfunction and infertility when used on a young male [9].

The most popular Inguinal hernia repair method in Nigeria is the Modified Bassini repair [10], and it is also the most practiced in sub-Saharan Africa, because it is simple to perform, the skill to perform it is abundant, even in rural hospitals; and very cheap [11]. The Desarda repair although novel, it seems to have met the criteria of an IDEAL hernia repair, does not use a prosthesis, the weakened conjoined muscles or transversalis fascia for repair. It is also cheap and carries lower complications rate [12]. This study was therefore conducted to compare the early and intermediate outcomes of the Modified Bassini and the Desarda hernia repair, with the aim of adopting the Desarda repair as a substitute for the costly Lichtenstein repair where the prosthetic mesh is unavailable.

II. PATIENTS AND METHODS

This is a randomised controlled trial, involving 50 adult patients, both males and females, that presented at the General Surgery unit of the State Specialist Hospital Potiskum, Yobe state, Nigeria. The study was conducted between July 2021-December 2021, as a single blinded, single centre, randomised controlled trial. Both elective and acute cases of Inguinal hernias admitted for surgery during the period were recruited. All patients 16 years of age and above (15 years and below is the cut off age for the hospital) were recruited. All patients with poor immune status, on cytotoxic chemotherapy, with bleeding diathesis and those with ECOG/WHO stage 4 performance status and those who declined consent for surgery were excluded. Informed consent was obtained according to the Helsinki guidelines and Ethical clearance was given by the hospital management.

Each patient was allocated to either the Modified Bassini or Desarda repair through balloting. The surgeries were conducted by the researchers under Local, regional or general anaesthesia, depending on the presentation and the duration of the hernia. Regional anaesthesia was used for long standing uncomplicated inguinal hernia because, of the possibility of incarceration from adhesions. All complicated cases were treated using general anaesthesia.

With patients in supine position, routine cleaning and draping is done, exposing only the operative area. An 8-10 cm oblique groin incision is used for each procedure and similar steps are taken through the subcutaneous tissue and external oblique aponeurosis as in standard text books.

The EOA is opened from the upper crux of the superficial ring to expose the arching fibres of the internal oblique muscle, which are retracted laterally to reach the spermatic cord. The cord dissection to separate the sac and subsequent herniotomy are similar for both procedures. The major difference is in the repair of the weak posterior wall of the inguinal canal. The medial leaf of the external oblique aponeurosis (EOA) was sutured to the shelving edge of the inguinal ligament from the pubic tubercle to the deep inguinal ring using Polyamide number 1 round body with continuous sutures. The first two sutures were taken from the anterior rectus

sheath where the EOA interdigitate with it; the last suture was taken with the aim of narrowing the internal ring in those with Nyhus type 2 hernia without constricting the spermatic cord.

Each suture was passed first through the inguinal ligament, then the transversalis fascia and the EOA. The index finger of the left hand was used to protect the femoral vessels and Collingwood Stewart hernia ring was used to retract the cord structures laterally while taking lateral sutures.

A splitting incision was made in the sutured medial leaf of the EOA, partially separating a strip from it with a width of 1.5 to 2 cm, equivalent to the gap between the muscle arch and the inguinal ligament. This splitting incision was extended medially up to the symphysis pubis and laterally up to 1-2 cm beyond the deep ring. The medial insertion and lateral continuation of EOA flap were kept intact. The upper free border of the strip of the EOA previously sutured to the inguinal ligament was later sutured to the conjoint tendon lying close to it with Polyamide number 1 with continuous sutures throughout its length. The aponeurotic portion of the internal oblique muscle was used for suturing to this strip to ensure a tension free suturing. The newly created strip of EOA was placed behind the cord to form a new posterior wall of the inguinal canal. Each patient was then asked to cough to demonstrate the increased tension on the strip exerted by the external oblique muscle. This increased tension exerted by the external oblique muscle was the bedrock of this repair. The spermatic cord was placed in the inguinal canal and the lateral leaf of the EOA was sutured to the newly formed medial leaf of the EOA in front of the cord again using Polyamide number 1 sutures. IF there is difficulty in a tension free suturing of the remaining upper lip of the EOA, undermining of the newly formed medial leaf of the EOA on both of its surfaces facilitate its approximation to the lateral leaf. The first stitch for the reconstruction of the anterior wall of the inguinal canal was taken between the lateral edge of the newly formed upper portion of the EOA and lower leaf of the EOA. This was followed by closure of the superficial fascia and the skin as usual.

In modified Bassini repair, the cord was retracted away from the posterior wall, and then interrupted polyamide 1/0 sutures were used to approximate the conjoint tendon to the medial lip of the inguinal ligament. The first stitch was put in the periosteum over the pubic tubercle. The sutures were placed at intervals of approximately 1cm between them. The most lateral suture is used to narrow the deep ring when it is dilated to <2cm. The cord was then placed back on the strengthened posterior wall of the canal. The aponeurosis of external oblique was repaired with continuous Vicryl 2/0 and the superficial ring reconstructed to match the size of the cord.

The early outcomes studied were duration of surgery, post-operative pain, duration of hospital stay, and early post-operative complications and recurrence. Early ambulation was encouraged postoperatively, beginning from 12 hours after surgery for those done under regional or general anaesthesia. Patients were given oral analgesia and prophylactic antibiotics were given for those with acute presentation. Sutures were removed on day 7. Follow-up was done at 1 week, 4 weeks, 3 months and 6 months. General and targeted physical examination was done during every visit to assess the early and intermediate outcomes. All data obtained was assessed using the Statistical Package for Social Sciences, version 20.0 (IBM, Armonk, NY, USA). Continuous variables were presented as mean ± SD. Categorical variables were expressed as frequencies and percentages.

The Pearson's chi square test was used to determine the relationship between two categorical variables. $P<0.05$ was considered statistically significant.

III. RESULTS

A total of fifty (50) subjects were recruited. Males constituted 92%, females 8%, giving a male-female ratio of 12:1. The mean age was 40.3 (+_2.98) and the age range was 18-75 years. A total of 44% presented with right sided inguinal hernia, 44%, had left sided inguinal hernia and the remaining 12% had bilateral inguinal hernia.

Half of the patients had an indirect inguinal hernia with a dilated deep ring (50%), 24% had a direct hernia, 18% had an indirect hernia with an intact deep ring, 8% had a pantaloon hernia and none had a femoral hernia. More than half of the patients (56%) were operated under spinal anaesthesia, 42% via local infiltration and one (1) patient was operated on using general anaesthesia. Twenty-five subjects each (50%), had the Modified Bassini repair and the Desarda No-mesh hernia repair respectively.

The surgery was done within 20-45 minutes in 62% of the subjects, within 45-60 minutes in 30% of the subjects, and in only 8% of the subjects that the surgery lasted for more than an hour. Pain was measured using the visual analogue scale (VAS), with 0-30 mm signifying mild pain, 31-60 mm moderate pain, 61-90 severe pain and 91-100 excruciating pain. Postoperative pain according to VAS (Mean ± SD) on day 1 was 31.2 (±02.0). Up to 68% of the subjects, experience mild to moderate post - operative pain, only 4% experienced severe pain (Figure 1). The severe pain was associated with the Modified Bassini Repair (Table 1).

There were no recorded intra-operative complications in 84% of the subjects. Only 6% each of the patients had Seroma and Haematoma respectively, and 4% developed Surgical Site Infection (Table 2). Both Seroma and Haematoma formation are more associated with the Desarda repair than Modified Bassini repair (Table 3).

More than half (56%) of the cases were done as Day Care Surgeries, 36% were discharged within 48 hours and only 6% stayed on admission for more than 48 hours (Table 4). All the patients that stayed for more than 48 hours had the Desarda hernia repair (Table 5). Majority of the patients (60%) achieved normal gait the 12 -24 hours after surgery and returned to work within the first week of the surgery, 28% within 2-3 weeks, only 12% took more than 3 weeks to resume normal work (Figure 2). Up to 83.3% of those who took more than 3 weeks to return to work are the patients with post-operative complications like seroma, haematoma or SSI (Table 6). The degree of posterior wall weakness and dilatation of the deep ring increases with age (Table 7). The weaker the posterior wall, the more dilated the deep ring, also the longer the duration of surgery. Most surgeries that lasted for an hour or above are also those with weaker posterior wall (Table 8). This relationship also translates into more post-operative complications, irrespective of the type of the procedure done (Table 9). No recurrence was recorded during the short period of the study (Figure 3).

IV. DISCUSSION

Inguinal hernia has remained a major problem in Africans, the demand for its surgical repaired has considerably surged forward through the years to the extent that it is mainly done as a day case procedure in most tertiary health centres; even in secondary and primary health facilities in order to satisfy this demand [13-14]. This fact has been adduced to as the cause of decline of prevalence of strangulated inguinal hernias or giant hernias [15-16]. A remarkable tribute to the tremendous work of our older generation of surgeons. The exact reasons for the high prevalence of Inguinal Hernia in adult male Africans has remained a mystery. Reports from East Africa suggested an anatomical susceptibility, particularly, the low pubic arch prevalent in most male Africans [17].

This is thought to weakens the pelvic Myopectineal fascial system [14]. In the study, males constituted 92% of the subjects, females 8%, giving a male-female ratio of 12:1. Other studies have also noticed a male preponderance for Inguinal hernia [18]. Perhaps, due to the descent of the Testes and the higher exposure of the male to strenuous physical activities. The mean age recorded was 40.3 (+_2.98), with an age range of 18-75 years. Gogler reported the age of 45 years as the age of peak incidence in Africans [19]. This may coincide with the age of onset of bladder outflow obstruction due to benign prostatic hyperplasia and also the beginning of the age related weakening of Fruchaud's pelvic Myopectineal orifices. The mean age reported by Gopal et.al was 46.7 also, and the age range was 16-85 years [18]. There seems to be no preponderant side for the Inguinal hernia in our study. The right sided and left sided

inguinal hernia occurred at 44% each, and the remaining 12% had bilateral inguinal hernia. Half of the patients had an indirect inguinal hernia with a dilated deep ring (50%), 24% had a direct hernia, 18% had an indirect hernia with an intact deep ring, 8% had a pantaloon hernia and none had a femoral hernia from the study. Some Authors have reported a slight preponderance of the Right-sided inguinal hernia (64%), followed by left-sided (28%) and bilateral (8%). This has been attributed to the late descent of the right testis. Perhaps, our small sample size may be the cause of such unusual finding. From our study, majority (68%) of the subjects presented with an indirect inguinal with significant dilatation of the deep ring and 8% had both the direct and indirect hernias on same side (pantaloon hernia). Desarda MP [20] himself also noticed the predominance of the Indirect type (74%), had similar proportion of the direct hernias as in our study but, a very small proportion of the pantaloon hernia. This pattern was also replicated in his second paper on the Desarda repair [21]. The wide age range beginning from 16 years and the predominance of the males at a ratio of 12:1 may explain the higher percentage of the indirect inguinal type in this study. The direct is often seen as an acquired case after a long duration of strenuous physical activity or multiple pregnancies in the female.

Regional spinal anaesthesia was our anaesthesia of choice, used on 56% of those operated, 42% via local infiltration and on 1 patient the general anaesthesia was used. Situma from Kampala-Uganda used local infiltration for both the Modifies Bassini and Desarda repair [5]. No reason was given for the choice of the local infiltration only. Gopal et.al [18], like us, used regional anaesthesia in96% of his patients, local anaesthesia was given to 4% of the patients. No general anaesthesia was used [18]. Desarda MP in ground breaking work [20] on 229 patients, used regional anaesthesia on 84% of the patients operated, 14.8% had the surgery under local and 0.43% under general anaesthesia. We chose regional anaesthesia because majority of our patients presented within 2 years or above after noticing the hernia; with very high risk of incarceration due to adhesions (Table 10). With a Pearson's chi square result of 0.000, less than p-value of 0.005; this is statistically significant. Equal number of patients had either Modified Bassini or Desarda repair, 50% each.

The mean duration of surgery was 48.08 (+_ 1.46) and in 62% of the patients, the surgery was done within 20-45 minutes, within 45-60 minutes in 30% of the subjects, and in only 8% of the subjects did the surgery lasted for more than an hour. Longer duration for surgery is associated with the Desarda repair. Up to 66.7% of surgeries that lasted between 45-60 minutes are the Desarda repairs and 100% of those that took more than an hour are the Desarda repairs (Table 11).

The need for raising a flap from the EOA, the increased number of suturing for reconstruction and the occasional need for undermining the remaining medial shelf of EOA as a advancement flap to allow for easy reconstruction of the anterior wall; will all account for the longer duration needed to perform the Desarda repair.

With a Pearson's chi square correlate of X^2= 0.016, the difference in duration is not statistically significant (Table 11). The mean operative period reported by Gopal et.al [18] was 54.86 minutes (range 40-120 minutes). Like our study, they completed up to 80% of the Desarda repairs within 60 minutes. The study by Mitura et al, comparing Lichtenstein and Desarda repairs, the mean duration for Desarda's repair was 56.6 minutes [22]. This is about 9 minutes longer than our mean duration. Perhaps, the choice of only Specialist Surgeons as the operators may account for our improved speed.

Our mean postoperative pain according to VAS (Mean ± SD) on day 1 was 31.2 (±02.0). Up to 68% of the subjects, experience mild to moderate post-operative pain, only 4% experienced severe pain (Figure 1). The severe pain was associated with the Modified Bassini Repair (Table 1). The work done by Mitura et al [22] reported a mean VAS score on a scale of 1-10 to be 3.3 on the first postoperative day in Desarda's group. This is similar to 33.0 on the scale we used, obviously a higher post-operative pain average. Manyilirah et al [23] also reported a mean post-operative pain

score based on VAS to be 2.73 (± 1.64) for Desarda's group. A slightly lower average than our study. They however, had a lower percentage of surgeries done under local anaesthetic infiltration.

Although the Desarda repair is associated with more dissection and a higher number of suturing, the lack of tension along the line of repair may be responsible for the decreased post-operative pain compared to the tension repairs.

Majority of the patients (60%) achieved normal gait and returned to work within the first week of the surgery, 28% within 2-3 weeks, only 12% took more than 3 weeks to resume normal work (Figure 2). Up to 83.3% of those who took more than 3 weeks to return to work are the patients with post-operative complications like seroma, haematoma or SSI (Table 6). Situma et.al at Kampala-Uganda, reported that, for both the groups in Modified Bassini and the Desarda repair, they achieved their normal gait by the 10th day after the surgery. The mean duration for the assumption of normal gait for the two groups was similar, at 3.62. The range for the Desarda group was 1 – 7 (6) days, and for the Bassini group was 1 –9 (8) days [5]. A result almost similar to ours was documented by Kyamanywa et al at Mulago hospital Uganda, after conducting a randomised trial comparing the Lichtenstein mesh repair with modified Bassini hernia repair [24]. The longer period before resumption of normal gait was noted in the Desarda group, especially, those who resumed after 3 weeks. But, it is evident that the delay was because of the post-operative complications recorded (Table 6). Both methods were considered to some degree to be tension methods by Situma et. al [5]. Tension is said to be created even in the seemingly tension free Desarda's technique, particularly, during the reconstruction of the anterior wall of the inguinal canal with the new medial edge of external oblique muscle and its lateral edge. This is the reason why undermining of the new medial edge as an advancement flap is strongly advocated [18,24,25]. No evidence of recurrence was seen during the short period of the study.

V. CONCLUSION

Although there is a slight difference in the mean operative time, post-operative pain and early return to work between the two methods of hernia repair; the difference is not statistically significant. The Desarda has the added advantage of having the qualities of Lichtenstein repair without the problems associated with the prosthetic mesh.

Recommendation: A randomised controlled trial comparing the Desarda No-mesh repair with the Lichtenstein repair should be done widely with the view of adopting the Desarda repair as the gold standard.

Conflict of interest: None declared

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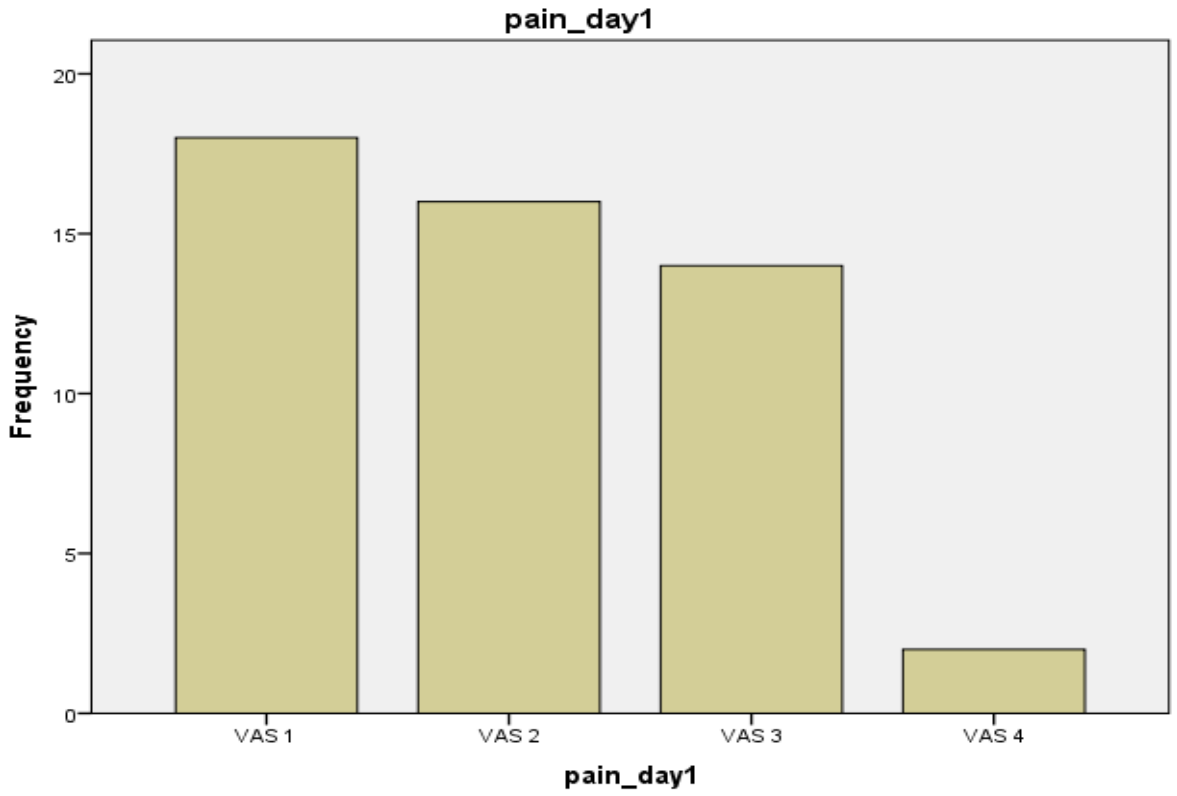

Figure 1: Showing the severity of post-operative pain on day one

Table 1: Showing relationship between the surgery type and pain

SURGERY	pain_day1				Total
	VAS 1	VAS 2	VAS 3	VAS 4	
modified bassini repair	9	7	7	2	25
desarda repair	9	9	7	0	25
Total	18	16	14	2	50

$X^2=0.522$, $P=0.005$

Table 2: Showing the distribution of complications

COMPLICATION	Frequency	Percent
Seroma	3	6.0
Haematoma	3	6.0
Wound infection	2	4.0
Nil	42	84.0
Total	50	100.0

Table 3: Showing relationship between surgery type and complications

SURGERY	complications				Total
	seroma	haematoma	wound infection	nil	
Modified bassini repair	1	1	1	22	25
Desarda repair	2	2	1	20	25
Total	3	3	2	42	50

$X^2=0.859$, $P=0.005$

Table 4: Showing distribution of hospital stay

HOSPITAL STAY	Frequency	Percent
Day case	29	58.0
2 Days	18	36.0
3 Days and above	3	6.0
Total	50	100.0

Table 5: Showing relationship between surgery type and hospital stay

SURGERY	hospital_stay			Total
	Day case	2 Days	3 Days and above	
Modified bassini repair	19	6	0	25
Desarda repair	10	12	3	25
Total	29	18	3	50

$X^2=0.020$, $P=0.005$

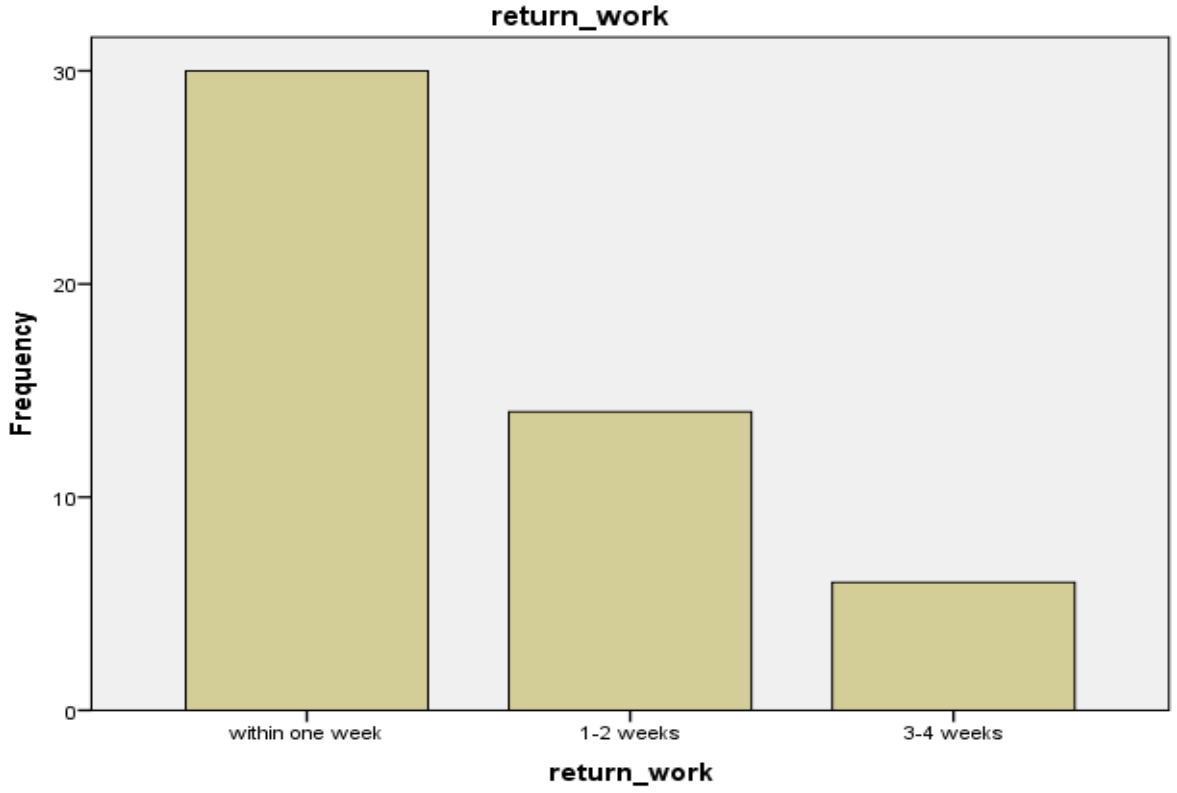

Figure 2: Showing the distribution of the days of return to work

Table 6: Showing relationship between return to work and complication

COMPLICATIONS	return_work			Total
	within one week	1-2 weeks	3-4 weeks	
Seroma	2	0	1	3
Haematoma	0	1	2	3
Wound infection	0	0	2	2
Nil	28	13	1	42
Total	30	14	6	50

$X^2=0.000$, $P=0.005$

Table 7: Showing relationship between age and posterior wall weakness

AGE	nyhus_type				Total
	indirect with intact deep ring	indriect with dilated deep ring	3	4	
16-25 years	5	2	1	0	8
26-35 years	4	9	0	1	14
36-45 years	0	10	1	1	12
46-55 years	0	3	4	0	7
56-65 years	0	1	3	1	5
66 and above	0	0	3	1	4
Total	9	25	12	4	50

X^2=0.000, P=0.005

Table 8: Showing relationship between posterior wall weakness and longer duration of surgery

	surgery_duration			Total
	30-45 minuts	45-60 minutes	60 minutes and above	
Indirect with intact deep ring	9	0	0	9
Indriect with dilated deep ring	17	6	2	25
3	5	6	1	12
4	0	3	1	4
Total	31	15	4	50

X^2= 0.020, P=0.005

Table 9: Showing relationship between degree of posterior wall weakness and post operative complications

NYHUS TYPE	complications				Total
	seroma	haematoma	wound infection	nil	
Indirect with intact deep ring	0	0	0	9	9
Indriect with dilated deep ring	2	1	2	20	25
3	1	0	0	11	12
4	0	2	0	2	4
Total	3	3	2	42	50

X^2= 0.031, P=0.005

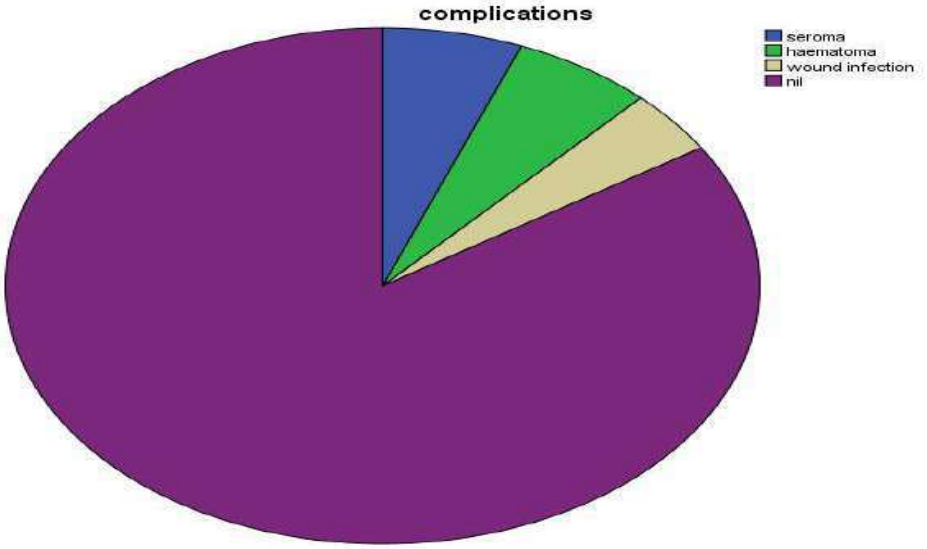

Figure 3: Showing the absence of recurrence during the study

Table 10: Showing relationship between hernia duration and anaesthesia used

ANAESTHESIA	surgery_duration			Total
	30-45 minuts	45-60 minutes	60 minutes and above	
Local	19	2	0	21
Spinal	12	13	3	28
General	0	0	1	1
Total	31	15	4	50

X^2=0.000, P=0.005

Table 11: Showing the relationship between surgery type and duration

SURGERY	surgery_duration			Total
	30-45 minuts	45-60 minutes	60 minutes and above	
Modified bassini repair	20	5	0	25
Desarda repair	11	10	4	25
Total	31	15	4	50

X^2=0.016, P=0.005