Original Article

Evaluation of the Effectiveness of Adjustable [Programmable] L-P Shunt Compared to the Conventional {Non Programmable} L-P Shunts Regarding Post-Operative Outcome and Complications in IIH

Wameedh Qays abdulhussein[1*], Mohammed Thakir Ismail Alkubaisi[2]

[1] Teaching Fellow at the Faculty of Medicine, University of Baghdad, Iraq. Email: dr.wameedhkais@yahoo.com
[2] Lecturer at the Faculty of Medicine, University of Ibn Sina for Medical Sciences, Iraq. Email: mhammedthakir@gmail.com

Abstract

Background: Surgical treatment of idiopathic intracranial hypertension (IIH) includes the use of L.P {lumboperitoneal} shunt have two type from L.P shunt. conventional one {non programmable} and second type adjustable (programmable) was introduced in the last decades. **Aim of the Study:** To evaluate the effectiveness of adjustable L-P shunt compared to the conventional {non programmable} L-P shunts regarding post-operative outcome and complications. **Patients and Methods:** This is cohort study [retrospective and prospective] single-center study of 58 patients with idiopathic intracranial hypertension treated in the neurosurgical department at the Martyr Ghazi Al-Hariri Hospital for Specialized Surgery for a period extending from August 16th, 2015 till November 26th, 2019. Patients had been referred to the neurosurgical unite from Baghdad city neuromedicine unit or from other centers. **Results:** This study has two-parts prospective used programmable L.P shunt for 33 patients), Second part retrospective used an old L.P shunt {non programmable} for 25 patients. 88% of the patients were female, with a mean age of 34 years and a high prevalence of obesity. All patients presented with headaches, papilledema, and visual disturbances, and underwent adjustable LP shunt placement, resulting in clinical improvement in 97% of cases for headaches and 85% for visual symptoms. Postoperative complications were minimal, with over-shunting and under-shunting being the most common issues. **Conclusions:** In conclusion, comparing the adjustable (programmable) LP shunt and conventional (non-programmable) when used to treat IIH has the P value non-significant regarding the infection, over drainage, revision and the CSF leak.

Keywords: Programmable, Non-programmable, L.P, Shunt.

Introduction

The use of the adjustable lumboperitoneal (LP) valve as part of an LP shunt system, indicated for the treatment of idiopathic intracranial hypertension.

The cranial cavity normally contains brain weighing approximately 1400 gm, 75ml of blood, and 75ml of CSF**.** Reciprocal change among these three various components (CSF, blood, brain tissue) in the intracranial space occur when the volume of one of these components is changed. So, if brain tissue mass increase due to swelling, the CSF volume must decrease, also the blood volume flow is decreased, later more serious sequelae occur.[1-5]

Idiopathic intracranial hypertension (IIH), sometimes referred to by an old name, "pseudotumor cerebri (PTC)", is a chronic neurological disorder, which can mimic the symptoms of a brain tumor.[6] IIH is characterized by increased intracranial pressure with no evidence of intracranial mass, hydrocephalus, infection, or hypertensive encephalopathy. It is a diagnosis made by systematically ruling out other disorders. The Modified Dandy Criteria is used to assist physicians in establishing the diagnosis.[7] The reported female-to-male ratio of 2:1 to 8:1 shows no gender difference in the juvenile form. Obesity is prevalent in 11–90% of cases, with lower prevalence in men. Among obese women of childbearing years, the incidence ranges from 19 to 21 per 100,000, compared to 1–2 per 100,000 in the general population.

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Address for Correspondence: Teaching Fellow at the Faculty of Medicine, University of Baghdad, Iraq. Email: dr.wameedhkais@yahoo.com

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The peak incidence occurs in the third decade, ranging from 1 to 55 years, with 37% of cases found in children, of which 90% are aged between 5 and 15 years, while it is very rare in infancy. Recurrence rates range from 9% to 43%, with the condition frequently being self-limited.[7]
Lumboperitoneal shunting; is an operation in which CSF is diverted from lumbar subarachnoid space into the peritoneal cavity by devices designed for this purpose using a simplified surgical technique. The reservoirs are designed to allow injection through the dome using a 25 –gauge or smaller needle.[8-11]
Surgery is employed when patients initially present with severe optic neuropathy or when other forms of treatment have failed to prevent visual loss. It is not recommended for the treatment of headaches alone.[12-21]
There is a lack of comprehensive data on the long-term efficacy and safety of adjustable lumboperitoneal (LP) valves in the treatment of idiopathic intracranial hypertension (IIH). Most studies, including the current one, focus on short-term clinical outcomes and complications, but do not adequately address the durability of symptom relief or the rate of recurrence over extended periods.
This study aims to evaluate the effectiveness of programmable L-P shunt compared to the traditional (non programmable) L-P shunts regarding post-operative outcomes and explore the differences in complication rates between the two aforementioned.

Patients and Methods

This is cohort study [retrospective and prospective] single-center study of 58 patients with idiopathic intracranial hypertension treated in the neurosurgical department at the Martyr Ghazi Al-Hariri Hospital for Specialized Surgery for a period extending from August 16th, 2015 till November 26st, 2019.
Patients had been referred to the neurosurgical unite from Baghdad city neuromedicine unite or from the nearby cities First part from study prospective of 33 patients with idiopathic intracranial hypertension from August 30th, 2017 till November 26st, 2019 treated with programmable L.P shunt.
Second part from study retrospective of 25 patient with idiopathic intracranial hypertension from August 16th, 2015 till August 30th, 2017 treated with old traditional L.P shunt.
Patients included in this study had been diagnosed as idiopathic intracranial hypertension (IIH) using the Modified Dandy Criteria. All of the patients were presented with headache and/or blurred vision, then examined for papilledema. Brain CT-scan and MRI were used to exclude any possible pathology. Intracranial pressure (ICP) measurement was performed using lumbar puncture and the obtained cerebrospinal fluid (CSF) was sent for laboratory analysis (appearance, glucose, protein, WBC count & differentiation).
Patients were included in this study who fulfilled the Modified Dandy Criteria, with normal brain CT-scan and MRI (other than slit ventricles), normal clear composition of CSF, and ICP measurement above 250 mmH_2O. Then, these group of patients were sent to the ophthalmological unit for further evaluation including visual field (perimetry), visual acuity, scotoma, nystagmus, abducens nerve palsy, the confirmation of papilledema, and to provide the degree of visual loss and severity of the optic neuropathy.
Exclusion of secondary pseudotumor cerebri (especially in children or non-obese women) by searching for other associated etiologies, like cerebral venous sinus thrombosis (requires MRV), or exogenous drug use or withdrawal (oral contraceptive, steroid, vitamin A, cimetidine, phenytoin, thyroid replacement therapy, specific antibiotics "like tetracycline, trimethoprim-sulfamethoxazole, ciprofloxacin"), endocrine and metabolic dysfunction or systemic illnesses (hypoparathyroidism, uremia, iron deficiency anemia, cushing's syndrome), and other conditions such as pregnancy.
After establishing the diagnosis, patients were offered conservative treatment using Acetazolamide (Diamox) oral tablets "250 mg twice a day" for a period of one month after excluding severe optic neuropathy.
Failure of the medical treatment (signified by unreduced CSF pressure and/or failure to prevent the ongoing visual loss) or in case of sever optic neuropathy, lumboperitoneal shunt (LP) operation was offered as an option of treatment (if there is no contraindication), especially for those complaining from headache, in which optic nerve sheath fenestration will not reduce the headache and have no effect on ICP. Those who agreed to undergo surgery were included in this study, after signing a consent and willingly agreed for the follow-up study.

Inclusion Criteria

- Confirmed diagnosis of IIH by the Modified Dandy Criteria.
- Failure of medical therapy and/or severe optic neuropathy.
- Absence of contraindications for LP shunt placement, such as congenital or acquired spinal deformities or infections in areas where shunt components will be implanted, including arachnoiditis from previous tapping.
- History of complications with previous conventional small lumen narrow-bore LP shunt without a valve, such as shunt obstruction, underdrainage, or overdrainage.

Exclusion Criteria

- Secondary pseudotumor cerebri where treating the underlying condition typically leads to improvement.
- Patients who decline shunting surgery or participation in the study or follow-up visits.

Surgical Technique and Follow Up

The surgical technique begins with positioning the patient laterally and administering general anesthesia and preoperative antibiotics. A small midline incision is made in the lumbar region, followed by insertion of a lumbar catheter into the subarachnoid space. A left abdominal paramedian incision exposes the peritoneum, while a left

flank incision is made for valve placement. The peritoneal catheter is passed from the abdominal incision to the loin incision, and the lumbar catheter is pulled through the loin incision to the lumbar incision. After connecting the catheters to the valve, they are secured and inserted into their respective spaces. Finally, all incisions are closed using absorbable and non-absorbable sutures.

Postoperative follow-up involves a 24-hour observation period in the neurosurgery ward to monitor for complications such as CSF collection or leaks. Patients receive IV antibiotics and analgesia, instructed to lie flat initially to prevent headaches, and encouraged to resume oral intake gradually. If no complications arise, patients can be discharged with oral antibiotics and analgesics, with instructions for wound care and a follow-up visit in a week for stitch removal and performance level reassessment. Patients are advised to avoid magnetic field exposure to the valve and attend a second follow-up visit three weeks postoperatively to assess symptoms, complications, magnetic field exposure, and to adjust the performance level if necessary. Any complications during the postoperative period prompt further medical attention. Postoperative valve adjustment using the StrataVarius® Adjustment System involves inserting the Smart Card, completing a self-test, aligning the system with the valve, adjusting lateral position, and confirming centering with a green light. The Performance Level setting and pressure are displayed, and the Adjustment Tool is positioned over the valve to change settings. After confirming changes, the Adjustment Tool is removed and steps are repeated if necessary for confirmation.

The data was analyzed using SPSS V.26 with 95% confidence level with p-value less than 0.05 indicating statistical significance. The descriptive statistics was done in form of mean, standard deviation and percentage, while chi-square test was applied to detect difference in complication rates between the traditional and programmable device.

Results

In this prospective study, 33 patients were enrolled when the diagnosis of idiopathic intracranial hypertension (IIH) was confirmed utilizing the Modified Dandy criteria and were treated by an adjustable LP valve.

Gender of the Patients

Female Patients: There are 29 female patients, which represents 88% of the total patient population. Male Patients: There are 4 male patients, which accounts for 12% of the total patient population. Total Number of Patients: The total number of patients is 33. In summary, the majority of the patients are female, making up 88% of the total, while male patients constitute only 12%.

Table 1: Gender of the Patients.

Female	Percentage	Male	Percentage	Total
29	88%	4	12%	33

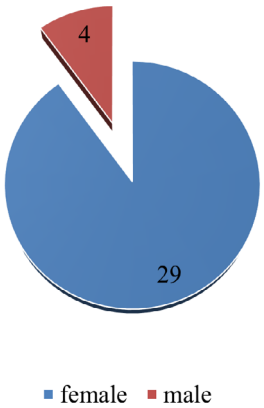

Figure 1: Gender of the Patients.

Age Distribution of Patients

Most patients are aged 21-30 years (46%) and 31-40 years (39%). The total number of patients is 33, with the majority (85%) between 21 and 40 years old as detailed in Table 2.

Table 2: Age Distribution of the Patients.

Age	No. of Patients	Percentage
11-20	1	3%
21-30	15	46%
31-40	13	39%
41-50	4	12%
Total	33	100%

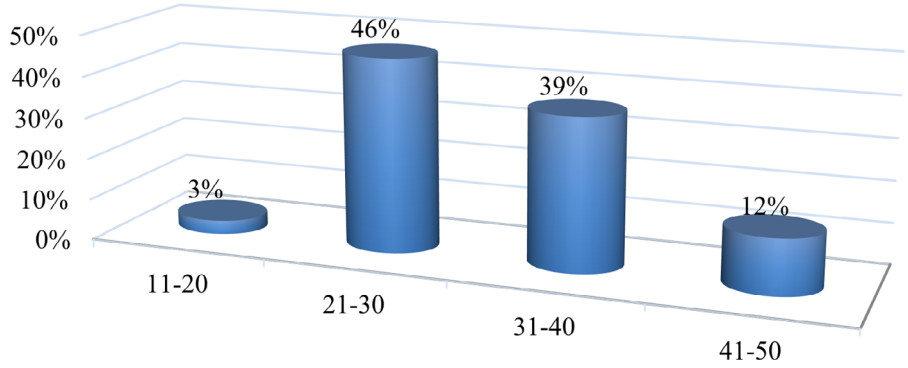

Figure 2: Age Distribution of the Patients.

Body Mass Index (BMI)

Most of the patients (46%) were presented with severe (35) or morbid obesity (40 and over) with a second large percentage of the cases (30%) being obese. While, one case (3%) was normal weight and 7 cases (21%) were overweight Table 3.

Table 3: BMI of the Patients.

BMI	No. of Patients	Percentage
18.5-24.9	1	3%
25-29.9	7	21%
30-34.9	10	30%
35 and over	15	46%
Total	33	100%

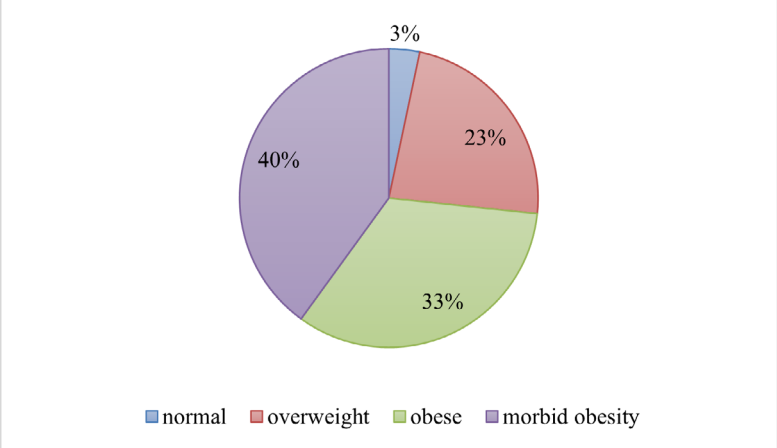

Figure 3: BMI of the Patients.

Table 4 Male patients have a BMI range of 23.9-27.9 (mean 26.1), while female patients have a higher BMI range of 26.9-44.6 (mean 34.1). Females generally have a higher BMI compared to males.

Table 4: BMI Range and Percentage in Relation to the Gender.

Gender	BMI Range	BMI mean
Male	23.9-27.9	26.1
Female	26.9-44.6	34.1
Total	23.9-44.6	33.3

Signs and Symptoms

Table 5 is showing the presenting features of the studied patients, all the patients were presented with headache and a percentage of 100%. Neck pain was presented in 14 cases (42%), visual disturbance in 29 cases (88%), nausea in 12 case (36%), and squint in 10 cases (30%). On examination Papilledema was definitively found in all (100%) patients. Other presenting features including tinnitus in 16 cases (48%) and dizziness in 14 cases (42%) were also obtained.

Table 5: Presenting Features.

Symptom / Sign	No. of Cases	Percentage
Headache	33	100%
Neck pain	14	42%
Visual disturbance	29	88%
Nausea	12	36%
Squint (6th n. palsy)	10	30%
Papilledema	33	100%
Tinnitus	16	48%
Dizziness	14	42%

CSF Opening Pressure and Analysis

This previously described group of patients were examined by lumbar puncture measurement for the opening intracranial pressure with the range of 280-585 mmH_2O (mean value of 374.5 mmH_2O). CSF appearance was clear in all patients and the analysis result of the obtained CSF showed glucose range 33-75 mg/dl (mean value 50.67 mg/dl) and protein range 21-55 (mean value 33.93) as detailed in Table 6.

Table 6: CSF Opening Pressure & Analysis.

Gender	Opening Pressure (mean)	Color	Glucose Range (mean)	Protein Range (mean)
Male	280-335 (331.67)	Clear	44-65 (55.3)	25-36 (29.67)
Female	285-585 (381.49)	Clear	33-75 (50.14)	21-55 (34.4)
Total	280-585 (374.5)	Clear	33-75 (50.67)	21-55 (33.93)

Valve Pressure Setting

The valve pressure was set pre-operatively as the initial performance level (P/L). One week later, during the 1st (follow-up visit), the valve pressure setting was adjusted according to the patient's condition as the 2nd P/L. Further two weeks later (during the 2nd follow-up visit), a third adjustment of the valve pressure was applied (when needed). Some patients required more than these two adjustments, and the final P/L was recorded. In other instances, the patient exposed to magnetic field and the final P/L was restored by re-adjusting the valve to the final recorded setting Table 7.

Table 7: The Performance Level (P/L) for Each Patient and Time of Surgery.

Case no.	Age	Gender	Opening Pressure	Initial P/L	Final P/L	Time of Surgery
1	47	Female	380	2.5	2.5	90 min
2	34	Female	360	2.5	2	2 hrs
3	25	Female	295	2.5	2	90 min
4	23	Female	440	2.5	2	105 min
5	50	Female	400	2.5	2	90 min
6	21	Female	350	2.5	2	2 hrs
7	45	Female	350	2.5	2	2 hrs
8	36	Female	365	2.5	2	90 min
9	37	Male	335	2.5	1.5	75 min
10	27	Female	400	2.5	1.5	2 hrs
11*	40	Female	540	2.5	1.5	2 hrs
12	32	Female	300	2.5	1.5	2 hrs
13	27	Female	390	2.5	1.5	90 min
14	17	Female	420	2.5	1.5	105 min
15	25	Male	320	2.5	1.5	2 hrs
16	28	Female	330	2.5	1.5	75 min
17	27	Female	375	2.5	1.5	80 min
18*	29	Female	320	2.5	1.5	110 min
19	38	Female	285	2.5	1.5	2 hrs
20	46	Female	585	2.5	1.5	90 min
21~	21	Female	410	2.5	1.5	2hrs
22*	32	Female	395	2	1.5	2 hrs 15 min
23	31	Female	400	2	1.5	90 min
24	24	Male	280	2	1.5	80 min
25	38	Female	330	2	1.5	2 hrs
26~	26	Female	420	2	1.5	75 min
27	37	Female	310	1.5	2	90 min
28	35	Female	420	1.5	1.5	2hrs
29~	28	Female	340	1.5	1	90 min
30	26	Female	390	1.5	1.5	110 min
31~	33	Male	320	2	1.5	90 min
32	26	Female	400	2	1.5	110 min
33	36	Female	380	2	2	100 min

The number of the cases according to the final recorded performance level in this study was one case (3%) with the pressure level 1 (45 mmH_2O "as appeared in the adjustment system"), 22 cases with the pressure level 1.5

(100 mmH_2O), 9 cases with the pressure setting 2 (155 mmH_2O), and one case with the pressure setting 2.5 (210 mmH_2O). None of them was (0%) with pressure level 0.5 (25 mmH_2O) as shown in Table 8.

Table 8: Number of the Cases According to the Final P/L.

Final Performance Level	Pressure Range	No. of Cases	Percentage
0.5	0-30 mmH_2O	0	0%
1	10-60 mmH_2O	1	3%
1.5	55-115 mmH_2O	22	67%
2	105-170 mmH_2O	9	27%
2.5	155-255 mmH_2O	1	3%

Average Time

When done average time found the 102.4 min. Also seen time surgery less time in male than female

Clinical Improvement

After an adjustable LP shunt was inserted, it is noticed in form of headache improvement in 32 cases (97%), and visual improvement (visual field or acuity) in 28 cases (85%. Table 9.

Table 9: Headache & Visual Improvement.

Gender	Headache Improvement (%)	Visual Improvement (%)
Male	3 (9 %)	4 (12%)
Female	29 (88%)	24 (73%)
Total	32 (97 %)	28 (85%)

Complications

As for the postoperative complications, overshunting was reported in 7 cases (21%), under shunting in 6 cases (18%), CSF collection in 3 cases (9%), infection in three cases (9 %), and the need for shunt revision in 2 cases (6%). Table 10.

Table 10: Complications.

Complication	No. of Cases	Percentage
Over shunting	7	21%
Under shunting	6	18%
CSF collection	3	9%
Infection	3	9%
Slipping upper end	1	3%
Slipping lower end	0	0%
Effected by magnetic	1	3%
Revision	4	12%
Subdural hematoma	0	0%

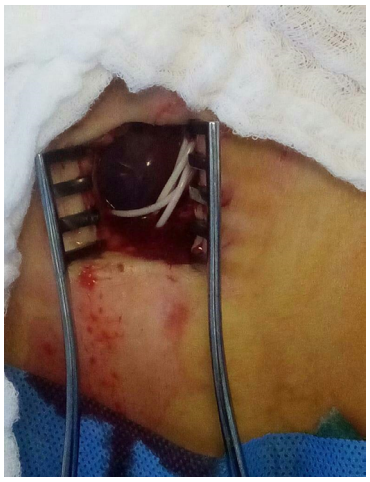

Figure 4: Slipping Upper End with Permission.

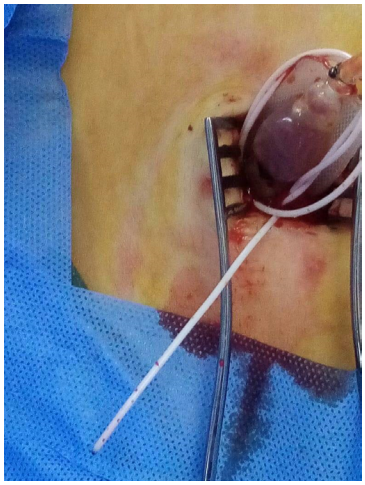

Figure 5: Slipping Upper end with Infected Programble Valve with Permission.

Second Part

A retrospective study for 25 patients treated with conventional (non-programmable) L.P shunt

Age

Figure 6 is describing the age ranged from 17-50 years, 11 patients were in the range of (30-39) and 8 in the range (20-29).

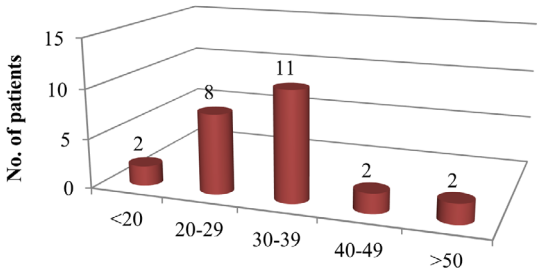

Figure 6: A Histogram Showing Age Distribution of Patients with LPS.

Age Distribution

Most patients are aged 30-39 years (44%), followed by 20-29 years (32%). There are 25 patients in total, with fewer patients in the younger (10-19 years, 8%) and older age groups (40-49 years and above 50, both 8%).

Table 11: Age Distribution.

Age (years)	10-19	20-29	30-39	40-49	Above50	Total
No. of cases	2	8	11	2	2	25
%	8	32	44	8	8	100

2. Gender

The majority of the patients are female (88%), with 22 females and 3 males, making up 12% of the total 25 patients.

Table 12: Sex Distribution.

Sexes	No. of Patients	Percentage
No. of Females	22	88%
No. of Males	3	12 %
Total	25	100%

Body Mass Index (BMI)

Most of the patients (44 %) were presented with severe or morbid obesity (35 and over) with second large percentage of the cases (32 %) were obese. While, one case (4 %) was normal weight and 5 cases (20 %) were overweight. Table 13.

Table 13: BMI of the Patients.

BMI	No. of Patients	Percentage
18.5-24.9	1	4%
25-29.9	5	20%
30-34.9	8	32%
35 and over	11	44%
Total	25	100%

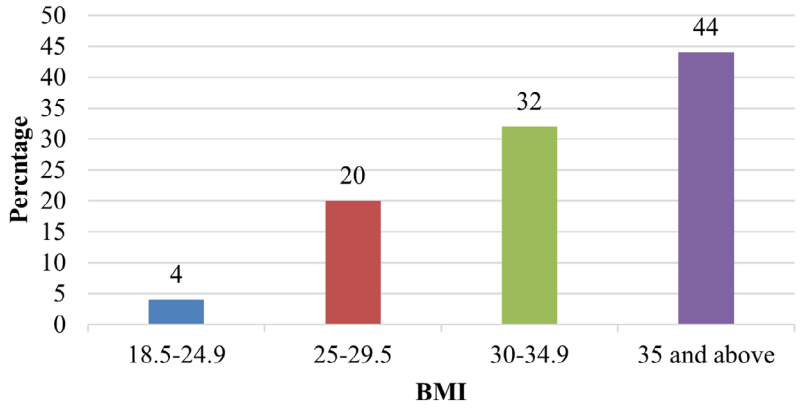

Figure 7: BMI of the Patients.

The body mass index (BMI) for this study was within the range of 23.9-44.6 with the mean value of 33.3. As for the male group of patients, they were normal or overweight. Overweight and obesity was noticed in all the female gender Table 14.

Table 14: BMI Range and Percentage in Relation to the Gender.

Gender	BMI Range	BMI mean
Male	23.9-27.9	26.1
Female	26.9-44.6	34.1
Total	23.9-44.6	33.3

Signs and Symptoms

Regarding the presented features of the studied patients, all the patients were presented with headache and a percentage of 100%. Neck pain was presented in 12 cases (48%), visual disturbance in 22 cases (88%), nausea in 9 case (36%), and squint in 8 cases (32%). Papilledema was definitively found in all patients. Other presenting features including tinnitus in 13 cases (52%) and dizziness in 10 cases (40%) were also obtained Table 15.

Table 15: Presenting Features of the Patients with all of them with Headache.

Symptom / Sign	No. of Cases	Percentage
Headache	25	100%
Neck pain	12	48%
Visual disturbance	22	88%
Nausea	9	36%
Squint (6th n. palsy)	8	32%
Papilledema	25	100%
Tinnitus	13	52%
Dizziness	10	40%

CSF Examination

CSF examination showed that all patients had clear appearance with pressure range between (220-410 mm water), shown in Table 16.

Table 16: CSF Examination Findings and time of Surgery.

Case No.	Appearance	Pressure mm H_2O	Age	Gender	Surgery Time
1	Clear	350	30	male	1hrs
2	Clear	365	32	Female	70 min
3	Clear	270	27	Female	75 min
4	Clear	280	25	Female	75 min
5	Clear	300	40	Female	1hr
6	Clear	320	45	Male	1 hr
7	Clear	270	35	Female	75 min
8	Clear	300	33	Female	90 min
9	Clear	300	29	Female	75 min
10	Clear	310	26	Female	70 min
11	Clear	270	42	Female	1 hr
12	Clear	300	33	Female	75 min
13	Clear	220	40	Female	70 min
14	Clear	340	30	Female	90 min
15	Clear	320	55	Male	70 min
16	Clear	310	29	Female	75 min
17	Clear	420	30	Female	90 min
18	Clear	400	30	Female	80 min
19	Clear	380	36	Female	75 min
20	Clear	370	40	Female	70 min
21	Clear	410	30	Female	1hr
22	Clear	330	35	Female	75 min
23	Clear	320	40	Female	1hrs
24	Clear	280	36	Female	70 min
25	Clear	290	32	Female	70 min

Average Time

When done average time found the 72 min. Also seen time surgery less time in male than female

Table 17 presents the headache improvement which was observed in 92% of patients (23 out of 25), with 80% of females and 12% of males reporting relief. Visual improvement was noted in 76% of patients, including 68% of females and 8% of males.

Table 18 shows that The most common complication was over-shunting, occurring in 28% of patients. CSF collection and slipping of the lower end occurred in 8% of cases, while slipping of the upper end, infection, subdural hematoma, and the need for revision surgery each affected 4% of patients. There were no cases of under-shunting or effects from magnetic exposure.

Table 17: Headache & Visual Improvement.

Gender	Headache Improvement (%)	Visual Improvement (%)
Male	3 (12%)	2 (8%)
Female	20 (80 %)	17 (68%)
Total	23 (92%)	19 (76%)

Table 18: Complications.

Complication	No. of Cases	Percentage
Over shunting	7	28%
Under shunting	0	0%
CSF collection	2	8 %
Infection	1	4%
Slipping upper end	1	4%
Slipping lower end	2	8%
Effected by magnetic	0	0%
Revision	4	16 %
Subdural hematoma	1	4 %

The difference between the two groups are shown in Table 19, none of the factors were significantly inferior to the programmable one.

- **Over-Shunting:** Occurred in 21% of patients with programmable shunts and 28% with non-programmable shunts (p = 0.5).
- **Under-Shunting:** Reported in 18% of patients with programmable shunts and 0% with non-programmable shunts, a statistically significant difference (p = 0.02).
- **CSF Collection:** Affected 9% of patients with programmable shunts and 8% with non-programmable shunts (p = 0.8).
- **Infection:** Occurred in 9% of patients with programmable shunts and 4% with non-programmable shunts (p = 0.4).
- **Slipping:** Slipping of the upper end occurred in 3% of patients with programmable shunts, while slipping of the lower end occurred in 0% of programmable and 8% of non-programmable shunts (p = 0.09).
- **Effected by Magnetic Field:** Affected 3% of patients with programmable shunts and 0% with non-programmable shunts (p = 0.3).
- **Revisions:** Required in 12% of patients with programmable shunts and 16% with non-programmable shunts (p = 0.7).
- **Subdural Hematoma:** Occurred in 0% of patients with programmable shunts and 4% with non-programmable shunts (p = 0.2).
- **Symptom Improvement:** Headache improvement was seen in 97% of patients with programmable shunts compared to 92% with non-programmable shunts (p = 0.3). Visual improvement was reported in 85% of patients with programmable shunts versus 76% with non-programmable shunts (p = 0.1).
- **Average Time:** The average surgical time was 102.4 minutes for programmable shunts and 72 minutes for non-programmable shunts.
- **Cost:** Programmable shunts were significantly more expensive, costing $2500 compared to $400 for non-programmable shunts.

Table 19: Comparative between Programmable and Non-programmable.

Complication	Adjustable (Programmable)	Conventional (Non programmable)	P-value
Over shunting	7 (21%)	7 (28%)	0.5
Under shunting*	6 (18%)	0 (0%)	0.02
CSF collection	3 (9%)	2 (8%)	0.8
Infection	3 (9%)	1 (4%)	0.4
Slipping upper end	1 (3%)	1 (4%)	0.8
Slipping lower end	0 (0%)	2 (8%)	0.09
Effected by magnetic	1 (3%)	0(0%)	0.3
Revision	4 (12%)	4 (16%)	0.7
Subdural hematoma	0 (0%)	1 (4%)	0.2
	Symptoms Improvement		
Headache	32 (97 %)	23 (92%)	0.3
Visual improvement	28 (85%)	17 (76%)	0.1
Time average	102.4 min	72 min	-
Cost	2500 $	400$	-

*: p-value for this group was statistically significant

Discussions

Our cohort study compared programmable and non-programmable shunts have two parts prospective 33 patients and retrospective 25 patients.

A total of 58 patients were included in our study, in which 51 of them were of female gender and the remaining 7 of them were male with female :male ratio was 9:1. Toma *et al.*[22] found the same female :male ratio of 9:1 with 18 female patients and only 2 males.[19] While, Yadav *et al.*[23] included 24 patients in their study, in which 22 of them were female with a female:male ratio of 11:1.This goes with the general concept of that there is female predominance concerning the idiopathic intracranial hypertension.

The age of the patients was in the range of 17-50 years with mean value of 32 years. Approximately, the same age range which was from 17-58 years (mean value of 39 years) was reported by Yadav *et al.*[23] in their series. The only difference was that one of the patients was of 58 years old. While, Alkherayf *et al.*[24] reported an age range of 23-46 years with a mean value of 33 years. But, their study included only 7 patients. In our study, we also found that the majority of the patients were in the age between 20-40 years (84%).

The range of the body mass index (BMI) was 23.9-44.6 with an average of 33.3. Data collected by Jusué-Torres *et al.*[25] was BMI average of 36 (range 30-41). We found that the incidence of the IIH is increasing with weight (73% of cases presented with BMI value of greater than 30).

Regarding the presenting features, headache was reported in 100% of cases, neck pain 43%, blurred vision 90%, nausea 37%, squint 30%, papilloedema 100%, tinnitus 50% and dizziness 43%. Yadav *et al.*[23] reported 100% of cases presented with headache & papilledema, visual deficit in 75% and diplopia 45%.[26] Abd-Ali *et al.*[27] reported headache in 100% of cases, blurred vision (visual disturbance) 86%, nausea & vomiting 40%, dizziness 20%, papilloedema 100%, squint (6th nerve palsy) 20%.[28] While, El-Saadany *et al.*[28] reported squint in 27% and bilateral

papilloedema in 91% of cases. Toma *et al.*[22] mentioned only headache in 90% & visual problem in 75% of cases. The small differences in these percentages are due to fact that some of the patients in these studies were already on a previous LP or VP

In our prospective study, we utilized programmable shunts. Selecting the initial performance level proved to be challenging. Despite attempting various methods to achieve optimal results, we found no discernible relationship between CSF opening pressure and the selection of an appropriate initial performance level, nor its impact on determining the final performance level.

Another challenge arose when setting the final performance level based on patient preference and their complaints of over- or under-drainage. Some patients struggled to differentiate between high-pressure and low-pressure headaches, necessitating the measurement of ICP from the valve itself using a 25-gauge needle while pressure was applied on the occluder. To address these issues, we suggest initiating with a performance level of 2.5, as we did in 70% of cases in our study. This approach allows any postoperative headaches to be considered as indicative of under-drainage, described as a reduction in severity but persisting. Most cases concluded with a final setting of 1.5 performance level (67%). Among the 33 patients included in our study, valve pressure adjustment was required in 12 patients during the postoperative period, often due to magnetic field exposure or difficulties in determining the optimal final setting. Alkherayf *et al.*[24] conducted a limited study involving 7 female patients, recommending an initial pressure setting of 1.5 performance level. However, 57% of these patients required adjustment by the 4th postoperative week. Adjustments to the 2.0 performance level were needed in 28.5% of cases, and to the 0.5 and 1.0 performance levels in one case each (14.25%). Three cases (43%) remained at the initial 1.5 performance level throughout.[24]

Headache improvement was observed in 97% of cases and visual improvement was recorded in 85% of cases by used programmable L.P shunt. while the valveless non programmable LP shunts improvement in our study headache 92% visual 76 %, the improvements for headache were 93.8 %, 91.7%, 86.4% & the visual 76.9%, 55%, 72.7% in the Yadav *et al.*[23], Abd-Ali *et al.*[23], and El-Saadany *et al.*[28] studies respectively.

Using a programmable valve LP shunt, the results were 100% & 86.7% regarding the visual improvement in the Alkherayf *et al.*[24] & Toma *et al.*[22] studies respectively. Meanwhile, the headache improvement was observed in 100% of cases in both latter mentioned studies (Toma *et al.*[22] also observed late postoperative headache in 4 patients, in which extensive workup including ICP monitoring & neurology opinion to exclude shunt related headache).[22,24] These results implies the concept that utilizing a programmable LP shunt leads to better outcome.

During the 2nd follow-up visit, occurring 3 weeks postoperatively or later, a second adjustment for the valve was necessary in cases of overshunting or undershunting (39%), which were rectified by adjusting the device. Additionally, CSF collection was encountered in 3 cases (9%), with 2 cases resolved by lowering the pressure setting and 1 case requiring surgical shunt revision due to infection. One instance of wound infection at the valve incision led to meningitis, diagnosed through ICP measurement and CSF analysis, resulting in shunt removal followed by antibiotic treatment. Shunt revision was required in 4 cases (12%), including one due to CSF collection and catheter disruption, another due to distal shunt obstruction caused by a pseudocyst, and the last due to upper end slippage.

CSF collection presented in 2 case 8 % treated conservative, one case presented with subdural hematoma treated by borehole drainage, revision shunt 4 case 12% one case over shunting 3 case slipping proximal end one case, obstruction distal end and slipping lower.

Yadav *et al.*[23], using valveless shunt system in 24 cases for 11 years, found CSF leak in 4% of cases, overdrainage 62.5% & shunt obstruction 8% (which was difficult to evaluate using intrathecal dye).[23] El-Saadany *et al.*[28], using also valveless shunt in 22 cases for 3 years, found infection in 9%, overdrainage 13.6% & shunt obstruction 27% (most of them due to migration of distal catheter).[29] Jusué-Torres *et al.*[25], using horizontal-vertical (H-V) lumbar valve in 26 patients for 20 years, found that 69% of the cases developed at least one complication (infection 8%, CSF leak 15%, overdrainage 35%, shunt obstruction 19%). Shunt revision was needed for 58% of cases (mostly due to overdrainage and tonsillar herniation),

Wang *et al.*[30] compared 46 patients treated with Integra H-V valve versus 21 patients treated with conventional valveless Silastic LP shunt, found that overdrainage was 8.6% in the first versus 33% in the latter.[30]

Toma *et al.*[22], using strata NSC programmable valve in 20 cases for 2 years, found distal end obstruction in 15%, proximal end obstruction 5%, CSF leak 5% (due to damage to the valve perioperatively). Shunt revision was done for 35% of cases (for the previous complications in addition to 10% of cases due to either valve malfunction "inability to adjust the valve", or suspected shunt disconnection by radiograph in which exploration revealed intact shunt system).[22]

When used p-value no found any significant differential statistics between post-operative complication and improvement symptom (headache, visual) after used L.P shunt conventional {non programmable} and adjustable (programmable).

Cost effective when used programmable L.P shunt about 2500 $ comparing with 400$ when used non programmable L.P shunt

Conclusions

In conclusion, comparing with the conventional one {non programmable} and second type adjustable (programmable) LP shunt when used to treat IIH has the same postoperative complication rates regarding the infection, over drainage, revision and the CSF leak.

- In programmable L.P shunt many causes could be

prevented or reduced like migration of the distal or proximal end (as those 2 ends are connected to a valve), distal end obstruction (as the valve permits using a different tube width for the peritoneal end).

- the Overdrainage could be easily reversed by readjusting the valve in programmable. In non-programmable the need for shunt revision or medical treatment.
- In programmable L.P shunt easier to evaluate the complications using a 25-gauge needle through the valve for intracranial pressure measurement, CSF sampling, dye injection to check the shunt patency comparing to the valveless 5 (non-programmable) LP system.
- Improvement symptom (headache and visual) non-significant differential statistic when used p-value
- Cost effective programmable L.P shunt about 2500 $ while non programmable 400$

Recommendations

- Encourage the use of a conventional one {non programmable} and adjustable (programmable) LP shunt to treat idiopathic intracranial hypertension.

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