VOLUME - 11, ISSUE - 02, FEBRUARY - 2022 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Opthalmology

A STUDY TO COMPARE THE CONTROL OF INTRAOCULAR PRESSURE IN PATIENTS OF REFRACTORY GLAUCOMA WITH VALVED (RESTRICTIVE) IMPLANT VERSUS NON-VALVED (NON RESTRICTIVE) IMPLANT

V.K. Baranwal (MS) Professor of ophthalmology and Commandant Military hospital , Jaipur ,Rajasthan, India.

Jitendra Kumar (MS) Professor , Dept. of ophthalmology, MLB Medical College Jhansi Uttar Pradesh, India.

Romil Gupta* (MBBS) Junior Resident, Dept. of ophthalmology, MLB Medical College Jhansi, Uttar Pradesh, India. *Corresponding Author

ABSTRACT

Purpose-. A study to compare the control of intraocular pressure in patients of refractory glaucoma with valved (restrictive) implant versus non - valved (non restrictive) implant **Methods**-This prospective, interventional and comparative study with parallel design enrolled a total of 80 cases of Refractory glaucoma and fulfilling the inclusion criteria who presented to the Department of Ophthalmology at Maharani Laxmi Bai Medical College, Jhansi from July 2020 - August 2021 (14 months duration) **Results-** In our study, majority of patients were in the fifth and six decade(42.50%) and both the study group has female predominance In our study,p value between mean of preoperative BCVA and 3 months postoperative BCVA was 0.88 for GROUP A which was not significant and p value between mean of preoperative BCVA and 3 months postoperative BCVA was 0.91 for GROUP B which was not significant. , p value between mean of preoperative NCT and 3 months postoperative was 0.005 for GROUP A, which was significant a p value between mean of preoperative NCT and 3 months postoperative was 0.004 for GROUP B which was significant . In GROUP A visual field defect was seen in 62.50% of patients preoperatively and in 65% of patients postoperatively at 3 months and in GROUP B visual field defect was seen in 65% of patients preoperatively and in 70% of patients postoperatively at 3 months **Conclusion-** This study was done to compare the outcome of valved and non – valved implants in both the study groups by preoperative and postoperative non-contact tonometry. In conclusion, both valved and non – valved implants cause a significant reduction of intraocular pressure post operatively, however non – valved implants show a better control of intraocular pressure than valved implants. The visual outcome is ,however similar of both the implants. This study however had certain limitations like requirement of a longer duration of follow up to look out for long term complications, which was not possible in our study due to time constraints. Also there was difficulty in conducting the study and in follow up due to the covid 19 pandemic. The future studies on the related subject can overcome these shortcomings if awareness regarding glaucoma surgery and glaucoma drainage implants is increased and the duration of the follow up is expanded so as to look out for further complications and final outcome of the drainage implants.

KEYWORDS : Glaucoma, Intraocular pressure, Valved implant, Non-valved implant

INTRODUCTION

Glaucoma is a group of eye disorders that lead to progressive damage to the nerve that connects the eye to the brain called the optic nerve. People with glaucoma can lose nerve tissue, resulting in vision loss.

The first attempt to implant a drainage device was made by Rollet and Moreau in 1907, when they performed a double paracentesis and used horse hair through the corneal punctures to treat patients with painful absolute glaucoma[1]. Later attempts include insertion of a polythene tube by Epstein in 1959, and silicon tube by MacDonald and Pearce in 1965. Molteno in 1969 scientifically explained the pathophysiology of bleb resistance and designed a tube[2]. Another significant development was in 1973 when Molteno improved his device with the idea of draining the fluid away from the limbus to increase the success rate. All of the currently available GDD are based on these fundamentals which were basis of Molteno implants[3]. The Molteno implants, however, offer no resistance to the outflow and post-operative complications like hypotony, flat ACs, and choroidal effusions were a regular phenomenon[4].

Types of implants

Non-valved/Non-restrictive implants:

- Single plate Molteno [SPM] implant
- Double plate Molteno (DPM)
- Baerveldt implant

2. Valved/Restrictive implants:

- Ahmed glaucoma valve
- Krupin slit Valved
- Others: Joseph, Optimed and White GDD.

3. GDD with variable resistance:

- Molteno dual ridge device

MATERIALS AND METHODS:

This prospective, interventional and comparative study with parallel design enrolled a total of 80 cases of Refractory glaucoma who presented to the Department of Ophthalmology at Maharani Laxmi Bai Medical College, Jhansi from July 2020 - August 2021 (14 months duration) Patient selection criterias are summarized as;

Inclusion Criteria:

All the patients who complied to the study protocol and gave the written consent in prescribed format were included in the study

- Age >18 years and <70years.
- Patients having uncontrolled intraocular pressure despite maximal antiglaucoma medication, previously failed nonseton surgical treatment, or a combination thereof.
- Patient insisting on surgical treatment (only one eye of the patient will be implanted with glaucoma valves)
- Glaucoma drainage device implantation is usually reserved for cases with refractory glaucoma, or those unlikely to respond successfully to a conventional filtration surgery
- Patients with preoperative clear cornea, well dilated pupils under medication, intact zonular apparatus
- Patients with confirmed negative RTPCR report for covid 19 infection

Exclusion Criteria:

Patient who refused to give a written consent or refused to abide by the routine follow up protocol were excluded from study

- Age <18 years and >70 years
- Visually significant ocular pathology
- Signs of corneal endothelial decompensation present
- Tear film instability
- Pupillary abnormalities
- Neuro ophthalmic diseases
- Eyes with severe scleral or sclera-limbal thinning
- Extensive fibrosis of conjunctiva
- Ciliary block glaucoma.
- Congenital and developmental glaucoma (responsive to conventional management)
- Pregnant female and lactating mothers.

Selection of cases:
A total of 85 patients who fulfilliled the inclusion criteria were selected for this study, out of which 5 patients were excluded (drop outs) at initial stage of study due to reason mentioned below. Finally a total of **80 enrolled patients** of either sex suffering from refractory glaucoma and fit for surgery (**Non-Valved and valved implant**) were evaluated and divided before intervention into one of the two treatment groups. **First group** comprising of **40 patients** underwent Non Valved implantation **second group** having another **40 patients** underwent Valved implantation

Slit lamp biomicroscopy:
Slit lamp biomicroscopy with diffuse illumination, focal illumination and retroillumination were used and a careful assessment of corneal transparency, anterior chamber examination for any evidence of uveitis.

Measurement of intraocular pressure:
Noncontact tonometer (NCT) was used to measure the preoperative and postoperative intraocular pressure in all the patient.

Fundus examination:
Fundus examination was done by direct / indirect ophthalmoscopy to rule out any co-existing retinal disease or any significant fundus changes

Gonioscopic examination:
Gonioscopic examination (by 3 mirror goniolens) was done preoperatively in all the patients to assess anterior chamber angle.

Perimetry:
Preoperative and postoperative at 3 months perimetry was done using Humphrey field analyser(HFA) to assess visual field and glaucomatous changes.

Pre-operative consent:
A written informed consent was taken from all the patients undergoing surgery, the procedure being explained to the patient about the type of surgery, type of glaucoma drainage device implanted and possible complications of the surgery

Follow up:
Postoperative evaluation was done at day 1, 1 week, 1 month, and 3 months. Uncorrected distance visual acuity(UDVA), best corrected visual acuity (BCVA), slit lamp biomicroscopy and intraocular pressure were noted at each follow up visit and visual field analysis by Humphrey perimetry was done at 3 months.

The study was followed in accordance with **Ethical Standards Committee** on human experimentation (institutional or regional) and abides by tenets of **Declaration of Helsinki (1975 and 2000 revision)**. Necessary permission from **Institutional Ethical and Research Committee** was obtained thereby.

Statistics:
Data was analysed by the Statistical Package for the Social Sciences (SPSS for windows, version 25.0). Descriptive statistics included mean and standard deviation for numerical variables, and the percentage of different categories for categorical variables.

Comparing of the results of the two types of valved and non valved implantation surgery for refractory glaucoma by Student's unpaired 't' test, the "p" value of <0.05 was indicative of a significant association.

RESULT:

Table 1: Mean Preoperative And Postoperative Bcva In Operated Eye

BCVA (logMAR)	Group A	Group B	p value
Preoperative	0.95±0.758	0.83±0.693	0.47 (NS)
Postoperative Day 1	1.03±0.753	0.90±0.690	0.44 (NS)
Postoperative 1 week	0.98±0.753	0.87±0.693	0.49 (NS)
Postoperative 1 month	0.96±0.752	0.85±0.693	0.50 (NS)
Postoperative 3 months	0.97±0.748	0.85±0.695	0.44 (NS)

Table 2: Mean Preoperative And Postoperative Intraocular Pressure (in Mmhg) In The Operated Eye

NCT	Group A	Group B	p value
Preoperative	29.70±1.636	29.85±1.955	0.71 (NS)
Postoperative Day 1	24.30±1.814	24.45±1.947	0.73 (NS)
Postoperative 1 Week	19.18±1.567	19.60±2.023	0.30 (NS)
Postoperative 1 Month	17.10±3.536	17.73±3.130	0.41 (NS)
Postoperative 3 months	16.58±3.448	19.53±3.630	0.003 (S)

Table 3: Preoperative And Postoperative Visual Field Defect Seen In The Hfa Report In The Operated Eye

Parameters	GROUP A		GROUP B	
	Preoperative	3 months postoperative	Preoperative	3 months Postoperative
1) PARACENTRAL SCOTOMA	8	8	10	9
2) SEIDEL SCOTOMA	5	5	7	8
3) ARCUATE SCOTOMA	6	7	4	4
4) DOUBLE ARCUATE SCOTOMA	5	5	4	5
5) TUNNEL VISION	1	1	1	2
TOTAL	25	26	26	28
PERCENAGES	62.50%	65%	65%	70%

Table 4: Complications After Galucoma Drainage Device Implantation In Patients

Post operative Complication	Group A				Group B			
	Day 1	1 week	1 month	3 months	Day 1	1 week	1 month	3 months
Corneal edema	10	0	0	0	6	4	1	0
Hyphema	10	6	3	0	8	3	0	0
Shallow anterior chamber	6	1	0	0	5	0	0	0
Increase intraocular pressure	0	0	1	1	0	0	5	5
Hypotony	0	0	2	2	0	0	1	1
Tube block	0	0	0	3	0	0	0	2
Diplopia	0	2	3	3	0	1	1	2
Endophthalmitis	0	0	0	0	0	0	0	0
Sub choroidal hemorrhage	0	0	0	0	0	0	0	0
Loss of vision	0	0	0	0	0	0	0	0
TOTAL	26	9	9	9	19	8	8	10

DISCUSSION

The use of **Glaucoma** Drainage device or implants (Valved and Nonvalved) has increased in recent years, especially relative to other surgical glaucoma procedures such as trabeculectomy[5,6].

Gender:

In our study the overall male female ratio was found to be 1:1.16(37:43). The number of cases were found singnificantly more in females(53.75%) than males(46.25%).

The Rotterdam Study demonstrated increased risk of primary open angle glaucoma (POAG) in women with early menopause[7]. Secondly, women were at higher risk for primary angle closure glaucoma (PACG) due to anatomical predisposition[8-11].

Best corrected visual acquity-

In our study, in Group A the mean preoperative BCVA was 0.95±0.758. It was 1.03±0.753 at day 1, 0.98±0.753 at 1 week , 0.96±0.752 at 1 month and 0.97±0.748 at 3 months postoperatively (p value 0.88). In Group B the mean preoperative BCVA was 0.83±0.693. It was 0.90±0.690 at day 1, 0.87±0.693 at 1 week , 0.85±0.693 at 1 month and 0.85±0.695 at 3 months postoperatively (0.91). The mean BCVA at 3 months postoperatively was 0.97±0.748 in Group A and 0.85±0.695 in Group B (p value 0.44). In our study the overall visual acuity remained unaffected except for 4 patients in Group A and 3 patients in Group B, who showed worsened visual acuity at 3 months follow up.

In the study by Nassiri N et al[12] st, those patients who successfully completed the trial (28 in the Molteno group and 29 in the Ahmed group) showed worsened visual acuity 24 months after surgery.

Intraocular pressure measured by noncontact tonometry-

In our study, in Group A there was a significant decrease in the intraocular pressure from 29.70±1.636 mmHg preoperatively to 16.58±3.448 mmHg at 3 months postoperatively (p value 0.005). In Group B there was a significant decrease in the intraocular pressure from 29.85±1.955 mmHg preoperatively to 19.53±3.630 mmHg at 3 months postoperatively (p value 0.004), implying a significant decrease in intraocular pressure after implantation of both valved and non valved drainage implant. At 3 months follow up the mean intraocular pressure was 16.58±3.448 mmHg in Group A and 19.53±3.630 mmHg in Group B (p value 0.003) ,implying a better intraocular pressure control in Group A (non valved implant) than in Group B (valved implant).

Nassiri N et al[12] study demonstrated that those who successfully completed the trial (28 in the Molteno group and 29 in the Ahmed group) achieved significantly less IOP and fewer glaucoma medications, but worse visual acuity 24 months after surgery. The Molteno group, compared with the Ahmed group, achieved significantly lower IOPs after the early postoperative period until the end of the study

Visual field defect by perimetry-

In our study, visual field defect were seen in 25 patients (62.50%) in GROUP A and 26 patients (65%) in GROUP B preoperatively and at 3 months postoperatively it increased to 26 patients (65%) in GROUP A and 28 patients (70%) in GROUP B

All the patients were advised 6 monthly follow up to monitor visual field changes as compared to baseline changes seen at time of presentation.

Nassiri N et al[12] in his study concluded that the Molteno group and the Ahmed group, Both reasonably maintained visual field during the follow-up in early postoperative period until the end of the study as compared to preoperative visual field defect.

Postoperative complication

In our study in Group A, at post-operative day 1 majority of patients showed corneal edema and hyphema which resolved over few days. Later on at 3rd month follow up few patients presented with tube blockage, diplopia, hypotony and increased intraocular pressure.

In Group B, at post-operative day 1 majority of patients showed corneal edema and hyphema and shallow anterior chamber which resolved over few days. Later on at 3rd month follow up few patients presented with increased intraocular pressure,tube blockage and diplopia.

In our study we had documented follow up and complications till 3 months postoperatively but all the patients were advised regular followup at 3 monthsly interval for life time to monitor control of intraocular pressure and deterioration of visual acuity, and progression of glaucomatous visual field and optic disc changes.

At each follow up patients are thoroughly evaluated for late complication of valve implantation surgery like tube exposure or extrusion, plate exposure, vitreous haemorrhage and uveitis

CONCLUSIONS

This study was done to compare the outcome of valved and non – valved implants in both the study groups by preoperative and postoperative non contact tonometry. In conclusion, both valved and non – valved implants cause a significant reduction of intraocular pressure post operatively, however non – valved implants show a better control of intraocular pressure than valved implants.The visual outcome is ,however similar of both the implants.

This study however had certain limitations like requirement of a longer duration of follow up to look out for long term complications, which was not possible in our study due to time constraints. Also there was difficulty in conducting the study and in follow up due to the covid 19 pandemic. The future studies on the related subject can overcome these shortcomings if awareness regarding glaucoma surgery and glaucoma drainage implants is increased and the duration of the follow up is expanded so as to look out for further complications and final outcome of the drainage implants.

REFERENCES:

1. Rollet M. Treatment da 1' hyperpyonpan le drainage capillaire de lar chamber antericive Rev Gen Ophthalmol 1906;25:481-9.
2. Molteno AC. New implant for draining in glaucoma. Br J Ophthalmol 1969;53:609.
3. Molteno AC, Straughan JL, Ancker E. Long tube implants in the management of glaucoma. S Afr Med J 1976;50:1062-
4. Brown RD, Cairns JE. Experience with the Molteno long tube implant. Trans Ophthalmol Soc U K 1983;103:297-312
5. Chen PP, Yamamoto T, Sawada A, Parrish RK 2nd, Kitazawa Y. Use of antifibrosis agents and glaucoma drainage devices in the American and Japanese Glaucoma Societies. J Glaucoma. 1997 Jun;6(3):192-6.
6. Joshi AB, Parrish RK, Feurer WI, 2002 Survey of the American Glaucoma Society, Practice preference for glaucoma surgery and antifibrotic use. J. Glaucoma 2005;14:172-174.
7. Hulsman CA, Westendorp IC, Ramrattan RS. Is open-angle glaucoma associated with early menopause? The Rotterdam Study. *Am J Epidemiol.* 2001 Jul 15;154(2):138–144.
8. Mark HH. Gender differences in glaucoma and ocular hypertension. *Arch Ophthalmol.* 2005 Feb;123(2):284. author reply 284.
9. Amerasinghe N, Aung T. Angle-closure: risk factors, diagnosis and treatment. *Prog Brain Res.* 2008;173:31–45.
10. Cedrone C, Mancino R, Cerulli A. Epidemiology of primary glaucoma: prevalence, incidence, and blinding effects. *Prog Brain Res.* 2008;173:3–14.
11. Quigley HA, Broman AT. The number of people with glaucoma worldwide in 2010 and 2020. *Br J Ophthalmol.* 2006 Mar;90(3):262–267.
12. Nassiri N, Kamali G, Rahnavardi M, Mohammadi B, Nassiri S, Rahmani L, Nassiri N. Ahmed glaucoma valve and single-plate Molteno implants in treatment of refractory glaucoma: a comparative study. Am J Ophthalmol. 2010 Jun;149(6):893-902.