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Original Research Paper

Surgery

CLINICAL STUDY OF INGUINAL HERNIA WITH SPECIAL REFERENCE TO COST OF TREATMENT

Dr.Tarun kumar Sainia	Assistant Professor, Department of Surgery L.N. Medical College and J.K. Hospital, Bhopal.
Dr. Shrikant Sharma	Assistant Professor, Department of Surgery L.N. Medical College and J.K. Hospital, Bhopal.
Dr Swagata Brahamchari	Professor, Department of Surgery L.N. Medical College and J.K. Hospital, Bhopal.
Dr Mahesh Ram	Assistant Professor, Department of Surgery L.N. Medical College and J.K. Hospital, Bhopal.

ABSTRACT

Aim: 1.To evaluate pre-operative, operative and postoperative cost in inguinal hernia, and to see the total cost of different operative procedures for management of inguinal hernia. 2. To evaluate the economic impact in relation to pre & post operative hospital stay.

Material and Methods : This study is a cost effectiveness analysis within a randomized controlled trial comparing open (OPEN) versus laparoscopic (LAP) hernia repair using mesh in Department of surgery with 6 months followup for each patient. Between January 2015 and September 2016. men with inguinal hernia were randomized and had an operation; patients (-75- OPEN and -25-LAP) with outpatient hernia operations were included in the cost effectiveness analysis. Outcomes included preoperative ,surgical and postoperative costs.

Results : Cost effectiveness analysis within a randomized controlled trial comparing open (OPEN) versus laparoscopic (LAP) hernia repair using mesh was done and it was seen that total cost in open hernia repair is 25958 [around 26000] whereas in laparoscopic it is 66478 .Significant difference was found in the intraoperative cost in open as compared to laparoscopic ,and there was also significant difference in the post op stay which wasmore in open repairs.

Conclusion : Laparoscopic repair although costly but has many advantages like small incision ,less hospital stay ,more patient satisfaction and early recovery. Open hernia repair though cost effective has limitations of large incision ,more hospital stay ,greater no of I.V. antibiotics and late recovery. But still in a poor ,developing country like India open method is still the method of preference as it involves significantly lower costs .

KEYWORDS : Laparoscopy Herniorrhaphy Costs Inguinal-hernia Charges

INTRODUCTION

Surgery has graduated from an art to science and has now become the basis of economics. In present scenario patient worries about cost, hospital stay, post operative rest & immobilization more than ever before.

Inguinal Hernias cause considerable inconvenience and are simple & safe to repair. They some times put the life of the patient in jeopardy due to their inherent complication of irreducibility, obstruction & strangulation. Repair of hernia is one of the most common routine & emergency surgical procedure. It is the second most common surgical procedure in the world

Maintaining the quality of surgical care along with ever mounting pressure to cut costs is the most challenging problem faced by the surgeons of developing world. In the best interest of the patients, the hernia repair should be effective, complication free, short duration of anaesthesia and related complication. The proposed steps of management should be performed with clearity in mind in the light of cost effectivity.

Open repair of hernia includes various methods using different suture material and prosthess (mesh); their cost ranging variably. These has been difference of opinion as to the choice of technique, suture method to be used, post operative recumbency& use of antibiotic which affect the economy of procedure.Both unrandomized & randomized studies have been conducted that compare the various procedure of tension free open herniorrhaphy. An economic evaluation of different surgical procedures has been included in these trials.

The economic status of our nation dictates that efforts to ensure the cost effectiveness of surgical operation should be reviewed in this era of spiraling health care cost and increased patient awareness of health care options, arises the need of cost evaluation.Surgeons of today have been able to introduce useful socioeconomic consideration in their own studies along with clinical efficacy. Laparosocpic hernia surgery being one of the revolution in this field.The present study is an attempt to evaluate the cost of various hernia repair conducted in our institution and to find out the socioeconomic status of each repair.

METHODOLOGY

The present study "Clinical study of Inguinal Hernia with Special reference to Cost of Treatment" was carried out in randomly selected 100 patients of Inguinal Hernia who were admitted in surgical wards of J.K. Hospital, associated with L.N. Medical College (M.P.) during the period Jan 2015 to September 2016.

All the cases presented with swelling in groin which were diagnosed as inguinal hernia on clinical grounds was included in this study. The patients was investigated as OPD patient and later on admitted in surgical wards for operation. Thorough clinical history of previous trauma and operations, details of postoperative recovery and complication indicating wound infection, dehiscence etc were carefully recorded. History of acute trauma, if present was noted. Causative factors were hereby highlightened. According to occupation officer staff, teacher, infants, children were included in sedentary group. Moderate group of people were shopkeepers, students, peons, and heavy natures of work were the group of people doing manual work such as famers, labourers, rickshaw pullers etc.

Besides the general parameters of the swelling an attempt was made to assess the reducibility and completeness of hernia, whether direct or indirect and contents of the hernia sac on the way to plane the necessary operative technique. Other common hernia sites were examined in every cases.The routine investigation done prosperatively in order to assess the condition of the patient for operation were Hb%, TLC, DLC, routine and microscopic urine examination. X-ray chest was done in all elderly patients as well as in those who complained of or presented with chronic cough or other chest complaints. X-ray abdomen was done in all emergency cases. E.C.G. and ultrasonography was done as and when required.

The patients presenting with irreducible hernia admitted as emergency cases were resuscitated with appropriate fluid supplementation, analgesics and sedation. Nasogastric intubation and urinary catheterization were done when indicated. Taxis was never attempted to reduce the irreducible swelling.In the patients where conservative treatment was successful surgery was planned and proposed during the same period of hospital stay or the patients were discharged and called afterwards. The latter group of patients were those who got themselves discharged on request mainly due to unwillingness of immediate surgery due to fear and/or inability to bear the cost of operation immediately. All these patients were sent with a word of caution that emergency could arise anywhere in future; hence negligence to their part could be disastrous.The patients willing for surgery were subjected to preanesthetic checkups and any major or minor aliment found during the check up was treated preoperatively. The type of surgery was planned according to the type of hernia.

The preoperative preliminaries of consent and premedication were completed and the proposed under anaesthesia. General anaesthesia with was employed few of emergency cases in adults and in all laparoscopic repair. Spinal anaesthesia was preferred in most of open hernia repair cases.

Depending upon the type of operation done the type of and amount of sutures employed for various operations by different surgeon was recorded. It was a matter of personal choice and on table decision of surgeon as per finding intra-operatively. Throughout the patients stay in the hospital right from admission to the discharge an account of everything spent over the patients management was maintained.

Cost evaluation was carried out in three phases for convenient analysis.

1. Preoperative hospital stay from admission to the day of operation, included admission/registration charges, cost of investigation an any preoperative drugs including fluids, antibiotics, analgesics etc. required per day. Every attempt was made to minimize preoperative stay of patients in the ward.

2. Operation charges including that spent on part preparation, operation theatre charges, premeditation, cost of anaesthesia and that of drugs and sutures used in the operation.

3. Cost evaluation of post operative period included the post operative fluids, drugs, and cost of management of any complication.

The cost of miscellaneous items like I.V canula, drip set, syringes, needles, Ryles tube, urinary catheter – urobag, drains etc. were also added to the total cost. The cost of item included both rate for hospital supply and market rate for item purchased from outside. The results of operation along with complications if any, were compared considering the general condition of the patient preoperatively, the type of operation done, suture materials used, mesh if used, and post operative management in light of the money spent in an average hernia repair.The patients were discharged and treated as OPD cases and followed up for complications if any and their cost added to the total cost of patient's management.

OBSERVATIONS

All the cases presented with swelling in groin were diagnosed as inguinal hernia on clinical grounds. The patient was investigated as OPD patient and latter on admitted in surgical wards for operation. Patients presenting with complication were also included in this study to complete the clinical profile.The cost of treatment was evaluated considering preoperative investigation, hospital stay, operative charges and pre and postoperative on the existing hospital rate and market rate of the drugs used. The following observations were made-

TABLE-1

DISTRIBUTION OF CASES ACCORDING TO INGUINAL HERNIA TYPE & SIDE INVOLVED

S. No.	Side	Direct No.	Indirect No.	Total No.
1	Right	10	20	60
2	Left	6	24	30
3	Bilateral	3	7	10
Total		**19**	**81**	**100**

It is evident from the above table that most of 60 cases had inguinal hernia on right side and were of indirect type in 50 patients.

TABLE 2 DISTRIBUTION OF CASES ACCORDING TO COST IN INGUINAL HERNIA IN PREOP

S No	COST OF	OPEN (In INR)	LAPROSCOPIC(In INR)	P value
1	Investigations(Blood & Urine investigations, X-Rays, Ultrasound, EGC etc)	**1500**	**1800(electrolytes extra**	**NS**
2	Pre operative Stay(1day)	**1500**	**1500**	**NS**
3	Pre OP preparation (part preparation, enema etc.)	**500**	**500**	**NS**
4	IV fluids & antibioitics	**1000**	**1000**	**NS**

P value and statistical significance:

The two-tailed P value equals 0.8472

By conventional criteria, this difference is considered to be not statistically significant.

Confidence interval:

The mean of Group One minus Group Two equals -75.00

95% confidence interval of this difference: From -987.14 to 837.14

TABLE 3 DISTRIBUTION OF CASES ACCORDING TO COST IN INTRA OPERATIVE

S No	COST OF	OPEN	LAPROSCOPIC(In INR)	P value
1	OT Charges(includes surgeon charge, anaesthesiologist charge&equipments charges)	5000	15000	SIG
2	Anaesthesia charges(includes drugs, inhalational agents, gases,etc)	2000	5000	SIG
3	Surgical Items (sutures ,gloves.cap,mask,betadine etc)	1000	800	NS
4	Mesh	1958(prolene hernia mesh)	5970(ultrapromesh)	SIG
5	HerniaTracker	-	28908	SIG

P value and statistical significance:

The two-tailed P value equals 1.1242

By conventional criteria, this difference is considered to be statistically significant.

Confidence interval:

The mean of Group One minus Group Two equals -9140.00

95% confidence interval of this difference: From -21413.06 to 3133.06

TABLE 4 DISTRIBUTION OF CASES ACCORDING TO COST IN POST OPERATIVE

S No	COST OF	OPEN	LAPROSCOPIC	P value
1	Catheterization	1000	1000	NS
2	IV fluids & antibioitics	3000	2000	NS
3	Post operative Stay	7500	3000	SIG

P value and statistical significance:
The two-tailed P value equals 0.4127
By conventional criteria, this difference is considered to be not statistically significant.

Confidence interval:
The mean of Group One minus Group Two equals 1833.33
95% confidence interval of this difference: From -3738.81 to 7405.47

RESULTS : Total cost in open hernia repair is 25958 [around 26000] whereas in laparoscopic it is 66478 **.** Cost effectiveness analysis within a randomized controlled trial comparing open (OPEN) versus laparoscopic (LAP) hernia repair using mesh was done and it was seen that total cost in open hernia repair is 25958 [around 26000] whereas in laparoscopic it is 66478 .Significant difference was found in the intraoperative cost in open as compared to laparoscopic ,and there was also significant difference in the post op stay which wasmore in open repairs.

STATISTICAL ANALYSIS
Statistical analysis was done by using SPSS software version 16. The data collected in the present study were presented in the form of tables and graphs. The data were analyzed statistically by calculating the descriptive statistics viz,. Mean, SD, percentage and 95% confidence interval for all continuous variables. The difference in mean is tested using independent sample student' s 't' test and the measures of association between the qualitative variables are assessed using chi square tests. The inference is considered statistically significant if $p<0.05$.

DISCUSSION
Inguinal hernia is one of the most common surgical conditions in India. The cost of health care related to the treatment of inguinal hernia and associated disability is substantial. Historically, hernias have been repaired by many different open surgical methods without universal consensus as to the optimal type of repair. Recent technologic developments have made laparoscopic herniorrhaphy possible. The introduction of laparoscopy for hernia repair has compounded the long-standing debate about the best type of repair. Determination of the most appropriate method of repair for any individual patient is not only medically correct but is particularly relevant at a time when health care costs are disproportionately escalating in relation to the gross national product.

Outcomes assessment must consider both short- and long-term results. Interpretation of clinical outcome studies may be restricted by such factors as study design, methodology, patient number, and adequacy of follow-up. Prospective, randomized, controlled trials are the premier standard in clinical research. Relatively few such studies on inguinal herniorrhaphy exist. The preponderance of data is based on less convincing evidence from nonrandomized trials with concurrent or historic controls or on accumulated case studies.[1]

K McCormack, B Wake et al did a systematic review of effectiveness and economic evaluation of Laparoscopic surgery for inguinal hernia repair. This review set out to determine: (1) whether laparoscopic methods are more effective and cost-effective than open mesh methods of inguinal hernia repair; and (2) whether laparoscopic transabdominal preperitoneal (TAPP) repair is more effective and cost-effective than laparoscopic totally extraperitoneal (TEP) repair of inguinal hernia. Where data allow, the patient population has been split by whether or not the hernia is recurrent or bilateral and whether or not the patient receives general anaesthesia.Laparoscopic inguinal hernia repair is a minimal access surgical procedure. Small incisions are made for the operating instruments and for a laparoscope. From the systematic review of economic evaluations, laparoscopic repair was more costly than open mesh in all but two of the 14 studies. Laparoscopic repair is more costly to the health service than open repair, with an estimated extra cost from studies conducted in the UK of about £300-350 per patient. The point estimates of cost provided by the economic model also suggest that the laparoscopic techniques are more costly (around £100-200 more per patient after 5 years).For recurrent hernias and treatment choice guided by gender and age, the data were sparse and results may be unreliable. In this circumstance, extrapolation from the base-case analysis for primary repair may provide the best available evidence. It is likely that, for management of symptomatic bilateral hernias, laparoscopic repair would be more cost-effective as differences in operation time (a key cost driver) may be reduced and differences in convalescence time are more marked (hence QALYs will increase) for laparoscopic compared with open mesh repair. When possible repair of contralateral occult hernias is taken into account, TEP repair is most likely to be considered cost-effective at threshold values for the cost per additional QALY above £20,000. Nonetheless, the results are sensitive to changes in estimates of prevalence and risk of progression of occult hernias, for both of which data are limited.[2]

McCormack K Wake B et al did a systematic review of effectiveness and economic evaluation in laparoscopic surgery for inguinal hernia repair.They studied totally extraperitoneal (TEP) repairs of inguinal hernias, despite having a favorable clinical outcome are often criticized due to higher costs and charges associated with this approach. Itemized direct costs, charges, and reimbursements were determined for 41 TEP and 44 OPN unilateral repairs done between January 1997 and December 1999. Multiple sensitivity analyses were done to evaluate the effect of cost-containment measures and the hospital's rate-setting policies on the differences in costs and charges between the two procedures. The hospital's profits were expressed as profit-cost ratios.

The mean direct cost for a TEP repair was $128.58 more than the OPN repair ($795.07[±65] vs 666.49 [±52]). However, mean charges and hospital reimbursement were $2,139.80 and $1,679.87, respectively, more for the TEP repairs. The profit-cost ratio was significantly higher in the TEP group (2.85:1 vs 1.07:1, $P<.001$). We found that 79.8% of the difference in direct costs vs 29% of the difference in charges between the two procedures was sensitive to cost-containment measures. Forty-five percent of the difference in charges was due to the hospital's nonuniform rate-setting policies. Long-term follow-up (38 months) showed no recurrence for either procedure. The direct cost of TEP repairs with the minimal use of disposable instruments in a high-volume center is comparable to the OPN repair. However, due to differences in the hospital's charging policies, TEP repair would appear to be an expensive alternative from the payer's point of view.[3]

Kevin T. Stroupe et al studied Cost Effectiveness of Laparoscopic Versus Open Mesh Hernia Operation after a Randomized Clinical Trial Evidence comparing laparoscopic versus open hernia repair has varied with time and with changes in techniques used. Cost effectiveness is an important consideration when evidence for predominance of one surgical technique is lacking. Current cost estimates of hernia repair are not available.This study is a cost effectiveness analysis within a randomized controlled trial comparing open (OPEN) versus laparoscopic (LAP) hernia repair using mesh at 14 Department of Veterans Affairs medical centers, with 2-year followup for each patient. Between January 1999 and November 2001, 2,164 men with inguinal hernia were randomized and 1,983 had an operation; 1,395 patients (708 OPEN and 687 LAP) with outpatient hernia operations were included in the cost effectiveness analysis. Outcomes included surgical and postoperative costs, quality adjusted life years (QALY), and incremental cost per QALY gained or the incremental cost

effectiveness ratio (ICER).Over 2 years, LAP cost an average of $638 more than OPEN. QALYs at 2 years were similar, resulting in $45,899 per QALY gained (95% CI: −$669,045, $722,457). The probability that LAP is cost effective at the $50,000 per QALY level (slightly more costly but more effective), was 51%. For unilateral primary and unilateral recurrent hernia repair, the probabilities that LAP is cost effective at the $50,000 per QALY level were 64% and 81%, respectively. For bilateral hernia repair, OPEN was less costly and more effective.Overall, laparoscopic hernia repair is not cost effective compared with open repair. For patients with unilateral (primary or recurrent) hernia, laparoscopic repair is a cost effective treatment option.[4]

Ms E. McIntosh didcost–utility analysis of open *versus* laparoscopic groin hernia repair .This study was a pragmatic economic evaluation carried out alongside a multicentre randomized controlled trial comparing laparoscopic with open groin hernia repair. The primary economic evaluation framework employed was a cost–utility analysis.At 26 hospitals in the UK and Ireland, 928 patients with a groin hernia were assigned randomly to laparoscopic or open repair. Cost data were identified and measured both within and outwith the trial. Cost data were combined with quality-adjusted life years (QALYs) from the EQ-5D questionnaire to obtain cost-per-QALY ratios.The mean cost of laparoscopic hernia repair was £1112·64, compared with £788·79 for the open operation. The extra cost of £323·85 in the laparoscopic group was mainly due to additional theatre time and increased equipment and sterilization costs. The estimated incremental cost per QALY of the laparoscopic over the open method was £55 548·00 (95 per cent confidence interval £47 216·00–£63 885·00).While the results show that a high cost was incurred to produce an additional QALY by using laparoscopic over open hernia repair, sensitivity analyses show that there are specific situations in which laparoscopic repair may be a viable alternative, such as when reusable equipment is employed.[5]

Luke Vale Adrian Grant et al did a study very similar to our study. They compared Cost-effectiveness of alternative methods of surgical repair of inguinal hernia.They found out that **open flat mesh was the most cost-effective method of preventing recurrences. Laparoscopic repair provided a shorter period of convalescence and less long-term pain compared with open flat mesh but was more costly. The mean incremental cost per additional day back at usual activities compared with open flat mesh was €38 and €80 for totally extraperitoneal and transabdominal preperitoneal repair, respectively.So they concluded that laparoscopic repair is not cost-effective compared with open flat mesh repair in terms of cost per recurrence avoided. Decisions about the use of laparoscopic repair depend on whether the benefits (reduced pain and earlier return to usual activities) outweigh the extra costs and intraoperative risks. On the evidence presented here, these extra costs are unlikely to be offset by the short-term benefits of laparoscopic repair.[6]**

Joseph B Mabula andPhillipo L Chalya did surgical management of inguinal hernias at Bugando Medical Centre in northwestern Tanzania which is a resource-limited setting .A total of 452 patients with inguinal hernias were enrolled in the study. All patients in this study underwent open herniorrhaphy. The majority of patients (61.5%) underwent elective herniorrhaphy under spinal anesthesia (69.2%). Inguinal hernias continue to be a source of morbidity and mortality in our centre. Early presentation and elective repair of inguinal hernias is pivotal in order to eliminate the morbidity and mortality associated with this very common problem.Their study issimilar to our study as we also are working in a limited resources set up.[7]

CONCLUSION

The present study "Clinical study of Inguinal Hernia with Special reference to Cost of Treatment" was carried out in 100 patients of Inguinal Hernia who was admitted in surgical wards .Hernia poses an important socioeconomic problem because of the restriction it imposes to active life, the disability which it cause, with loss of gainful employment an hazards life. Therefore considering the exsisting constrains in the medical college hospital today, an attempt was made to evaluate cost of treatment of hernia by open vs laparoscopic method of surgery.Relevant literature was reviewed. All patient on admission were interrogated, examined, investigated and managed surgically.Cost of treatment was evaluated by adding the cost of investigation, hospital stay, operation charges, pre and post operative medication on the basis of hospital rates prevailing during period of study and market rate for the item purchased from market. Laparoscopic repair though costly has many advantages like small incision ,less hospital stay ,more patient satisfaction and early recovery. Open hernia repair though cost effective has limitations of large incision, more hospital stay,greater no of I.V. antibiotics and late recovery. Still medical college hospital of central India caters majority of low socio economic andof middle class population and a very few number of rich population.Hence open hernia repair using mesh being more economical ismost widely performed surgical method in developing like country India.

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