



COMPARATIVE EVALUATION OF MINIMAL INVASIVE SURGERY WITH STANDARDIZED TECHNIQUE IN PATIENTS WITH TRAUMATIC BRAIN INJURY: A RANDOMIZED TRIAL

Neurosurgery

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ABSTRACT

BACKGROUND: TBI is a neurological emergency requiring surgical intervention at times. Traditional surgeries are associated with lots of complications. Hence, there is a need for a less invasive and yet effective surgical approach for TBI mass lesions.

METHODS: A total of 60 patients (30 patients in each surgical group) with mild to moderate acute TBI who fulfilled the inclusion and exclusion criteria were enrolled in the study over a period of 17 months.

RESULTS: There was statistically significant difference in the duration of operation, pain score, incision length ($p < 0.0001$ each) and hospital stay ($p = 0.0064$) which was significantly lower in Minimal invasive surgery (MIS) group.

CONCLUSION: Minimal invasive surgery has statistically significant advantage over standardized surgery in the terms of being done under local anesthesia, shorter duration of operation, shorter incision length, decreased post operative pain and shorter hospital stay. There was no clear advantage in terms of GOS and GCS

KEYWORDS

Minimal invasive surgery (MIS), Traumatic brain injury (TBI), Glasgow coma scale (GCS), Glasgow outcome scale (GOS),

INTRODUCTION: Traumatic brain injury (TBI) is a major health burden especially in the adult population. It is estimated that nearly 1 million persons are injured, 200,000 people die and nearly 1 million require rehabilitation services every year in India. At the global level, it is estimated that the annual incidence and mortality from acquired brain injury or traumatic brain injuries (TBI) is 200 and 20 per 1,00,000 per year, respectively. The data also shows that the majority of these individuals are males, in their early years (5 - 44 years) and most often they are involved in road traffic injuries^[1]

The damage to the brain from TBI is traditionally divided into primary and secondary injuries. Traumatic brain injury includes fracture of skull, concussion, cerebral laceration and contusion, subarachnoid, subdural, and extradural hemorrhage, other unspecified intracranial hemorrhage after injury along with intracranial injury of other unspecified nature according to ICD 9 codes.^[2,3] TBI are classified according to the Glasgow Coma Scale (GCS) into mild (13-15), moderate (9-12) and severe (3-8).^[4]

The management modalities include medical and surgical intervention. Traditional surgeries include large craniotomy or craniectomy based approaches. Conventional surgeries for TBI include craniotomy, craniectomy and decompressive craniectomy. In patients with traumatic intra cranial hematomas, conventional craniotomy has a mortality rate of 22%–36% and 44%–74% of patients who had undergone the procedure had poor outcomes.^[5] These procedures produce more pain, longer stay in hospital, and bigger scar. Also these traditional procedures are associated with neurological complications such as focal neurological deficits or cognitive impairment later on after surgery.^[6]

Minimal invasive surgery (MIS) is a surgical procedure done in a manner that causes little trauma or injury to the patient and involves small incisions, lesser bleeding, smaller amounts of anesthesia with quicker surgery, less pain, rapid recovery, and minimal cognitive impairment.^[7] MIS includes wide spectra of techniques ranging from finer trephination surgeries; endoscopic to imaging assisted surgeries.^[8] These surgeries overcome the disadvantages of the traditional surgeries in TBI like larger brain damage and bone flaps to name a few; however they require a higher level of expertise and expensive equipments.^[7]

TBI is a neurological emergency requiring surgical intervention at times. Traditional surgeries are associated with lots of complications. There is a need for a less invasive and yet effective surgical approach for TBI mass lesions. This randomized study was designed to compare

the outcome of patients with mild to moderate TBI treated with standardized surgery with those who are treated with a minimal invasive surgical approach.

MATERIAL AND METHODS:

This randomized controlled interventional study was conducted in Department of Neurosurgery, Safdarjung Hospital and Vardhman Mahavir Medical College, New Delhi. A total of 60 adult patients with mild to moderate acute TBI who fulfilled the inclusion and exclusion criteria were enrolled over a period of 17 months after written informed consent. They randomized to include 30 patients in each of the surgical groups. Inclusion criteria were age >18 years, GCS \geq 9 Mild to moderate acute TBI (contusions and intracerebral hematomas in frontal, temporal, parietal, occipital lobes). Exclusion Criteria were Age <18 years, GCS < 9, with other major chest, abdomen or long bones injury, co-morbidities (uncontrolled DM, HT, coagulopathies, cyanotic heart diseases etc.) and hemodynamically unstable patients. After history taking, examination, investigations and diagnosis, patients were randomly allocated to both the arms using the closed envelope technique. Thirty patients in had undergone standardised surgery where as the rest 30 underwent minimal invasive surgery. Study was approved by Institutional Ethical Committee. Standardized surgery included craniotomy or craniectomy under general anaesthesia. All the steps of standard craniotomy were followed. In Minimal invasive surgery (MIS) group, all cases were done either under local anaesthesia and sedation with intravenous propofol or general anaesthesia. General anaesthesia was given if operation had to be converted to standard craniotomy or craniectomy. Procedure for MIS in this study included a small skin incision, preferably in skin crease depending on the location of hematoma. Patients were evaluated both intra-operatively and post-operatively and during follow up. Post operative pain was assessed using Wong-Baker face scale. Patients who showed signs of failure on MIS were subjected to standardized techniques of craniotomy and craniectomy.

STATISTICAL ANALYSIS:

The data was analysis using Statistical Package for Social Sciences (SPSS) version 19.0. Quantitative variables were compared using Independent T test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups. Qualitative variables were correlated using Chi-Square test/Fisher's exact test. Univariate and multivariate logistic regression was used to assess the significant factors that leads to late admission. A p value of <0.05 was considered statistically significant.

RESULTS:

Our study population comprised of middle aged adults with a median

age of 40 years, ranged from 26-55 years. Total males in this study were 42 (70%) while 18 females (30%) were incorporated out of which 19 (63.3%) males underwent MIS compared to 11 (36.7%) females. Among standardized surgery, males were 23 (76.7 %) and females were 7 (23.3 %). Two patients in the MIS group had intra operative complication so the excluded from MIS group. Hence twenty eight cases were left in MIS group. The patients in the MIS group and standardized surgery group were comparable with respect to demographic profile. The median age and the gender distribution within the two groups had no statistically significant difference and thus reduce the confounding factors in this study.

In our study, most of the patients were operated in the range of 12-36 hours of injury, i.e. 75.0% in MIS group and 90% in Standardised surgery group. We found a significant difference between two groups ($p=0.0006$). Most of the lesions were in frontal and temporal regions in this study (82.2% in MIS group as compared to 70% in standardized group). There was no statistical difference between the two groups ($p=0.2029$). Lesions in occipital, parietal and posterior fossa were 17.8% and 30% in MIS and standardized groups respectively.

Most of the lesions were contusions in this study (85.7% in MIS group as compared to 66.7% in standardized group). Extradural Hematoma(EDH) was found in 4 cases (14.3%) of MIS and 10 cases (33.3%) of standardized group. There was no statistical difference between the two groups ($p=0.1626$). We found no statistical difference in neurological status of patients as indicated by GCS was 12.0 in MIS as compared to 14.0 in standardized group. No significant statistical difference was found in midline shift (MLS) between the two groups with values of 8 (6.5-12) in MIS and 6.2(4.9-7.7) in standardized group.

There was statistically significant difference in the duration of operation incision length in between the two groups ($p<0.0001$) each. The duration of operation was shorter in MIS group (45.0-60.0min) as compared to standardized group (90.0- 100.0minutes). The incision length was shorter in MIS group ($4.9\pm 0.5\text{cm}$) as compared to standardized group ($11.0\pm 1.4\text{cm}$). There was no significant difference in GCS on first post operative day in between the two groups and both groups had good GCS with no neurological deterioration. While pain was significantly lower in MIS group of patients may be due to smaller wound ($p<0.0001$).

There was no statistically significant difference between the rates of hematoma evacuation in the two groups ($p=0.6471$) as assessed by NCCT head on first operative day. Both the groups showed similar changes in GCS after the operation on first post operative day not significant ($p=0.0738$).

The pain score was still significantly lower in MIS group ($p<0.0001$). The pain had reduced in both the groups. Also there was statistically significant difference between the two groups due to lesser pain score in MIS group of patients, as all patients of MIS group have score of three or less while it is seen in only 60% of standardized group of patients. The GCS was comparable in between the two groups after one week of operation. Pain was statistically significantly lower in MIS group at one week of operation ($p<0.0001$).

There was no statistical significant difference found in volume of residual lesion between the two groups at the end of one week. The difference in wound status at one week of operation was not statistically significant. Although MIS group of patients had mild bruising in 3 (10.7%) and erythema with slight inflammation in 1(3.6%) of the patients. In standardized group of patients, we found wound infection in 2(6.7%) of cases and mild bruising in 3 (10.0%) and erythema with slight inflammation in 2 (6.7%) of the patients ($p=0.4159$).

There was no statistically significant difference in incidence of complication between the two groups. No cases of death or reoperation were seen in either of the groups. New neurological deficits were observed in 4 cases (14.3%) of MIS and two cases (6.7%) of standardized group. This included slowness of mentation, dementia, and irritability. No motor deficits were seen in this study. Surgical site infection and subcutaneous/subgaleal collection were seen in 1(3.3%) and 2 (6.7%) cases of standardized group, respectively ($p=0.5648$).

Patients in both the groups had similar GCS and GOS at one month

after operation. Also there was no pain in either of the groups ($p=ns$). Glasgow outcome scale (GOS) was assessed at 1 month after surgery in both groups of patients. All the patients in both minimal invasive and standardized surgery group had a good outcome of 5 with only 1 patient in the minimal invasive and 2 patients in standardised group had a GOS of 4.

All patients with MIS had excellent cosmetic outcome with fine imperceptible scar in skin crease / folds/ hairline and is of shorter length. While in standardized group, 86.7% patients have excellent cosmetic outcome while 13.3% had good outcome may be due to larger scars, not conforming to skin creases or skin infection in two cases. Though, the difference was not statistically significant ($p=ns$). For majority of patients who underwent MIS i.e. 20 (62.0%) hospital stay was 3-4 days. Only two (7.1%) patients in stayed for 1week. For patients in standardised surgery group, most patients i.e. 22 (73.4%) stayed for 4-5 days while 4 (13.3%) patients stayed for 7 days. The difference was statistically significant ($P=0.0064$).

The GCS change from first to third day was more in MIS group, with change of 2-4 values was seen in 3(10.7%) of patients ($p=0.5230$). In two of the patients in the minimal invasive group, the surgery had to be converted to standard surgery due to acute persistent bleeding in one case and incomplete evacuation of hematoma in second case. The failure rate of minimal invasive group in our study was 2 out of 30 patients i.e. 6.7%.

DISCUSSION:

All patients presenting to the hospital having a traumatic brain injury (TBI) with indications that warranted neurosurgical intervention were included in this study. Despite minimal invasive surgery being widely reported in the recent literature^[9-11] as valuable adjunct surgery for traumatic brain injury, standardized surgery is still generally considered as a common treatment modality.^[12-14] Although the subjective perceptions of neurosurgeons using MIS have been favorable, no large prospective studies evaluating the possible benefits to patients has been performed. We have attempted to assess the clinical effectiveness of minimal invasive surgery for the treatment of mild to moderate acute TBI in comparison to standardized surgery.

In our study, The population age ranged from 26-55 years. This is in concordance to the previous reports of Indian population wherein 34.3% of TBI occur in 26-40 yrs group and other reported literature throughout the world which indicate a high incidence of TBI in the middle age group.^[15-19] The male patients accounted for 70% of cases while female 30% of cases in our sample population. Similar results were obtained in other epidemiologic studies wherein male population accounts for 68.9-85 % of TBI and females almost for 25-31.1%.^[16-19] On comparison of the standardized and MIS patients, there were no statistically significant differences in demographic profile vis-à-vis age and sex distribution between the two groups. Thus the patients in the MIS and standardized surgery group matched in their demographic characteristics.

Most of the patients in our study population were operated in the range of 12-36 hours of injury with no patients presenting within the first six hours of injury. Similar results were obtained by Gururaj et al. in an epidemiological study that 35% cases presented in 12-18 hours, 33 % cases 18-24 hours, 24 % cases 6-12 hours, 5 % cases 0-6 hours and 3% cases of time of occurrence of injury was unknown.^[15] But our results are in contrast to Liu at al. 2006 who found that 12 of the 13 patients studied presented within the first 6 hours of injury but his study comprised of only 13 patients with extradural hematoma.^[20] The time since occurrence of injury is important prognostic factor. On comparison of MIS and standardized groups, no statistical difference was obtained. Thus the patients in the MIS and standardized surgery group matched in their time since injury presentation. The incidence of different sites in our study population in descending order was frontal>temporal> parietal>occipital>posterior fossa. Clearly frontal and temporal site of lesion form the major bulk of cases of TBI. In a neuroimaging study, similar results were obtained that 41.3% of cases in frontal lobe, 37.9% in temporal lobe, 10.3% in parietal lobe and 8.3 % in occipital lobe.^[21] This indicates probably more propensity of a frontal site of lesion in TBI patients. The two groups were similar and matched in the site of lesion also as there were no statistically significant differences between the MIS and standardized surgery site of lesion distribution.

In 75.9% of cases in our study population the type of lesion was contusion, while 24.1% cases had extradural hematomas. Our results are in concordance with other epidemiological studies which have also found that incidence of contusions >extradural hematomas >subdural hematoma.^[15,22] The MIS and standardized surgery group were matched in type of lesion with no statistically significant difference between them. On comparison between the MIS and standardized surgery groups, the GCS score was found to be lower in MIS than the standardized surgery group but no statistical significant difference. The two groups had a statistically significant difference in the total duration of operation. The time required for operation was found to be less in the MIS group than the standardized surgery group. This is probably suggest that minimal invasive surgery is less time consuming.

Minimal invasive surgeries are known for their small incisions during surgery.^[7] In our study also the MIS group had a smaller incision length as compared to standardized surgery group. This difference in both groups was found to be statistically significant in our study. Smaller incision length could result in less post-op morbidity in terms of infections, scars, other complications due to excessive handling and better cosmetic outcome.^[23]

To measure the effectiveness of the two operative procedures – GCS score was assessed one day after operation, there was no statistical significant difference between the MIS and standardized groups. These results probably indicate equal effectiveness of both the surgical technique. Our results are contrary to results of Nagasaka et al. who studied 40 patients with intracranial hemorrhage treated with MIS (n=20) and standard craniotomy (n=20) and found that mean GCS score at day 7 was 12 for the endoscopy group and 9.1 for the craniotomy group (P < 0.05) and concluded that endoscopic group had a better GCS score than standard craniotomy probably due to less invasive surgery.^[11]

Most of the patients in the study had a moderate degree of pain post-operatively (score of 5). MIS group patients had a lesser degree of pain as compared to standardized surgery group. Most patients had a pain score of 3-4 in MIS group while in the standardized surgery maximum patients had a score of 5. There was a statistically significant difference in the pain score between MIS and standardized surgery group. Pain is an important factor contributing to post-operative morbidity. Other studies have also reported less pain, shorter hospital stays, and reduced morbidity in minimal invasive surgery, not only in abdominal surgery but also in cardiothoracic, vascular, cerebral, and major orthopaedic procedures.^[24-26]

Both the surgical procedures – MIS and standardized surgery proved to be equally effective in terms of hematoma evacuation rate as there were no statistically significant difference obtained between the two groups. Our results is different from Nagasaka et al. 2011 who found that in endoscopic surgery median evacuation rate of hematoma was 99% and in craniotomy group was 95.9 % and concluded that endoscopy had a better hematoma removal than the standard technique.^[11] The two surgical groups had no statistically significant difference in the change in GCS on post-operative day 1 indicating equal effectiveness. The only comparative study in literature that we could retrieve found a mean GCS score change at day 7 of +4.8 in endoscopy group while -0.1 in craniotomy group.^[11] but this study included spontaneous intracranial hematoma, endoscopy as a minimal invasive surgery and GCS score assessment done at day 7.

Minimal invasive surgery and standardized surgery group patients had similar GCS score on third post-operative day with no statistical significant difference. This could probably suggest that neurological status improvement in both the surgical groups is equally efficient. The pain score in both minimal invasive surgery and standardized surgery had reduced. But there was a statistically significant difference between the two groups with a lesser pain score in MIS group of patients than standardized surgery. Although the overall GCS score between the two groups was not statistically different on day 3 and after 1week postoperative. Thus the two operative techniques had a similar effect on neurological status of patients.

This is in conflict with the study of Nagasaka et al. who found a better GCS in MIS than standard surgery group.^[11] The minimal invasive surgery group experienced less pain as compared to standardized surgery group with statistically significant differences between them. Maximum patients in MIS group had a score of 0-1 while in

standardized surgery group had a score of 2-4. The residual volume between the two groups had no statistically significant difference indicating that MIS and standardized surgery were equally successful in reducing/removing the hematoma. Nagasaka et al. 2011 found that hematoma evacuation was better in MIS group than standard surgery but this study differed in its study population and type of minimal invasive surgery which was endoscopy.^[11]

MIS group patients had lesser incision length than standardized surgery group but the post-operative wound status of patients at 1 week between the two groups had no statistically significant differences. It probably suggests that healing of wound irrespective of incision length is comparable between the two groups. The MIS group and standardized surgery group did not differ in the incidence of post-operative complications with no statistically significant differences between the two groups. In a study with a similar design comparing MIS (endoscopy) with standard surgery, they also found that the complication rate was same between the two groups.^[11]

The disability grading based on Glasgow outcome scale was comparable within the two groups with no statistically significant results. Similar profile was observed in the Glasgow coma scale based neurological assessment. Thus minimal invasive surgery and standardized surgery group seem to result in a similar post-operative clinical outcome. Our results match with the study of Nagasaka et al.^[11] where they found no statistically significant difference in the GOS score between MIS and standard surgery group at second month post-operative. Length of incision differed between the groups but the wound status was similar in both operative procedures and similar results were observed in the cosmetic outcome. Even though in minimal invasive surgery group all patients had an excellent cosmetic outcome while in a standardized surgery group had both excellent and good cosmetic outcome. Minimal invasive surgery group had a significantly less length of stay (≤ 3 days) in hospital than standardized surgery group. Literature suggests that minimal invasive surgery in general is associated with shortening of hospitalization procedures.^[26-28] and our findings are identical in this aspect with minimal invasive surgery group having an early discharge from hospital as compared to standard surgery group.

Minimal invasive surgery had a failure rate of 6.7 % this rate seems low in comparison to study by Liu et al. who performed a burr hole based evacuation and drainage for 13 patient with epidural hematoma and found that in 2 patients that is 15.3 % cases craniotomy had to be performed due to deterioration in their clinical status.^[20]

CONCLUSIONS:

Minimal invasive surgery has showed statistically significant advantage over standardized surgery in the terms of being done under local anesthesia, along with shorter duration of operation, shorter incision length, and decreased post operative pain and having shorter hospital stay. There was no clear advantage in terms of Glasgow outcome scale and further studies are required to prove the role of MIS.

LIMITATIONS OF THE STUDY:

Less number of patients was taken hence, Further studies are required with larger number of patients to further establish the results.

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CONFLICTS OF INTEREST: There are no conflicts of interest.

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