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A randomized study of twist drill versus burr hole craniostomy for treatment of chronic subdural hematomas in 100 patients

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Abstract: Chronic subdural hematoma (CSDH) has been treated by a variety of surgical approaches like twist drill craniostomy (TDC), burr hole craniostomy (BHC), craniotomy, etc. There are large variations in cure rates and recurrence rates among the surgical options in literature and like all surgical techniques, there is a paucity of well-designed trials to sort out the issue. It is an accepted fact of surgery that the least invasive approach will often be the best approach. We set out with the hypothesis that TDC is as safe and as effective as BHC for CSDH treatment. A prospective randomized controlled trial for 100 patients was done to compare the results of TDC and BHC (both with drain) in patients of unilateral CSDH. Recurrence rate was the primary outcome variable evaluated. A strict clinic-radiological criteria was used to avoid ambiguity in the study. Forty-eight patients underwent TDC and 52 patients underwent BHC. Mortality was 2% (patients in low GCS), and 2% unexpected mortality occurred (unrelated causes). Complication rate was 14% overall and was similar in both groups. Overall outcome (primary and secondary) was comparable across both groups with no significant difference. Cost, invasiveness and duration of surgery was significantly less in the TDC group. The cure rate, recurrence rate, mortality and morbidity of TDC with drain is significantly similar to that of BHC with drain for treatment of defined patients of unilateral sub-acute and chronic subdural hematoma. The cost, duration and invasiveness of TDC surgery is significantly less than that for BHC surgery.

Keywords: burr hole; chronic subdural hematoma; twist drill

INTRODUCTION

Chronic subdural hematoma (CSDH) is one of the most common intracranial hematoma in the elderly. The incidence is 1–2 per 100000 population per year and the treatment of this disease is therefore of great importance[1,2].

Risk factors include old age, alcohol abuse, seizures, anticoagulation and patients at risk for falls. Formation is thought to occur after minor trauma resulting in an acute subdural hematoma, which is often asymptomatic. The acute blood may resolve spontaneously or it may liquefy and continue to enlarge, developing into a subacute and chronic subdural hematoma. With further expansion of the subdural space there is further bleeding due to rupture of small bridging veins. Within 1-3 weeks the collection tends to be compartmentalized by development of a membrane around it. Bilateral clots occur in about 20% cases.

Various treatment options have been described viz. craniotomy, burr hole craniostomy (BHC), twist drill craniostomy (TDC), endoscopy and medical management for small hematomas[1-10].

However, there is a lack of clear consensus in literature regarding the optimum treatment for newly diagnosed subacute and chronic subdural haematomas. Burr hole craniostomy seems to have been the most commonly performed procedure for decompressing chronic subdural haematomas within the past 20 years. Recurrence rates of 6.6 to 38% and mortality rates of 3.8% have been quoted. TDC is the second commonest type of surgery done for such cases with reported recurrence rates of 6.7 to 29% and mortality rates of 3% [2-5]. Craniotomy is usually reserved for cases of multiple recurrences or where there is a large acute clot component[7].

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Surgery is usually done under day care/general anesthesia in the OT. Twist drill craniostomy may be done in the procedure room or bedside (in emergency cases) under local anesthesia. The major advantage of this technique is that it can be performed at the patient's bedside with the use of local anesthesia. The added factors of time and cost savings may be an added advantage. The complication rate is as low as other modern surgical techniques[2].

There are some studies which have attempted to compare twist drill craniostomy with burr hole craniostomy for CSDH treatment[5], but these have been indirect comparisons depending more on statistical models and hence cannot provide class I evidence. Other studies[11-16] have attempted to evaluate the results of either form of treatment and variously have studied the role of medical management[14], utility of drainage[16] and the causes of recurrence[13].

Only one study till date has directly compared the two commonest modes of treatment[19], where the authors concluded that there was no significant difference in outcome between the two forms of treatment. No studies have been published which can provide type A recommendations favoring either procedure. We undertook this study with the aim of comparing these two procedures with special emphasis on the above variables, with the hypothesis that recurrence rates after either procedure are similar and the ultimate choice of procedure will depend on other factors like invasiveness, cost, complications, duration of surgery, etc.

MATERIALS AND METHODS

This study was designed as a randomized prospective trial. Since complete blinding is impossible in any surgical trial, we undertook to remove bias as far as possible by third party blinding in as such that the person filling up the discharge and one-month follow up forms was blinded to the type of intervention done.

The primary outcome variable studied was clinically significant recurrence rate, which effectively translates to need for re-aspiration/ re-do surgery.

The need for re aspiration was clearly defined as: Re-aspiration needed- to be done before discharge if patient does not reach MGS grade 0 or 1, and CT scan shows residual fluid or air greater than 10mm thick with any midline shift; or after discharge if there is recurrence of or increase in symptoms (headache, hemiparesis, altered mentation) and CT scan shows residual fluid or air greater than 10mm thick with any midline shift.

Secondary outcome variables studied were –

1. GCS and Markwalder grade at discharge
2. GOS and Markwalder grade at 1 month follow-up
3. Time of surgery- prepping up to dressing
4. Radiological assessment at admission, discharge and at follow-up – regarding hematoma thickness and midline shift.
5. Complications–respiratory, cardiac, wound infection, subdural hematoma formation, cortical damage

Ethical clearance was obtained from the institutional ethical committee. The trial was listed with the Clinical Trial Registry of India (CTRI) [regn No. CTRI/2010/091/000359]. After obtaining informed consent for trial participation from the patients or their attendants, the patients were enrolled in the study.

Inclusion criteria: 100 consecutive patients presenting to our neurosurgery department between 01-04-2010 and 31-03-2011 with CT scan or MRI showing significant hemispheric subdural hematoma (>10mm thick).

Exclusion criteria:

Thin SDH (<10mm)
Small/ Unilobar SDH or post craniotomy SDH
Infants or cases of birth related subdural collections
Radiological doubt of hygroma/ empyema
Bilateral significant lesions (for ease of analysis)
Large acute clot component (organized hyperdensity)*

The patients were randomized using the *Startrek* random number generator into two arms and operated.

Surgical procedure: Patients in arm 1 underwent double (frontal and parietal) twist drill craniostomy of diameter 4mm (using a twist drill or hand held patented cranial perforator and introducer system) and irrigation with gentamycin mixed saline under local anesthesia (plain lignocaine) with insertion of a soft ventricular catheter (outer diameter 2.8mm) closed system drain in the subdural space.

Patients in arm 2 underwent standard double burr hole craniostomy (14–16 mm diameter) with similar irrigation and insertion of similar drain under monitored anesthesia in presence of the anesthetist. Anticonvulsant was given in all cases till follow-up. Uniform preoperative and post operative antibiotics to be used in all cases (2 days ceftriaxone plus amikacin/ gentamycin, followed by oral cefixime till discharge, or till clinical condition required modification). Post-operative bed rest in the supine position for 36 hours+/- 6 hours was enforced. Indwelling foley catheter was inserted till the patient was ambulatory.

Recurrences were treated by percutaneous needle aspiration the first time and burr craniostomy for a second recurrence.

Pre operative demographic profile (age, sex) and relevant medical, drug and trauma (diabetes, hypertension, CAD, CVA) history was taken. Detailed clinical examination (CNS, respiratory, cardiac, DVT), hematological (Hb, TLC, DLC, coagulation profile and hepatic viral markers) and other investigation were evaluated. Any component transfusion needed was done before randomization.

All details were recorded in 4 charts specially prepared for this purpose.

RESULTS

There were 52 patients in the burr hole (BHC) arm and 48 patients in the twist drill (TDC) arm. There were 5 females in each group. Mean age in BHC group was 61.2 years and was 59.8 in the TDC group. This difference was not significant (p=0.12). Overall there were 12 females and 88 males. History of diabetes was elicited in 2%, hypertension in 6%, alcoholism in 18% and trauma (preceeding 3 months) in 58% patients overall. There was no difference between the two treatment arms as regards these factors (p>0.05). Anticoagulant use was reported in only 1 patient. Three patients were lost to follow-up – one was a destitute patient, second was a prisoner and another was a patient of schizophrenia. All were in the BHC arm. 94% patients had a good outcome (KPS>90, GOS >4 and MGS <1) at 1 month.

Mortality (30- day) occurred in 4 patients (4%)-all in the twist drill arm. One was a patient of RHD who expired at home on the twelfth post-operative day after being discharged in GCS 15. The second was readmitted with Steven-Johnsons syndrome due to phenytoin and expired in hospital on the 20th post-operative day. The other 2 patients were admitted in GCS E1V1M2 and did not improve after surgery. Both expired within 4 days of surgery.

Admission GCS was 12.52 in the BHC group and 11.87 in the TDC group. At discharge, which occurred at an average of 7.38 days in the BHC group and 8.38 days in the TDC group, the mean GCS score was 14.96 in BHC and 14.52 in TDC arms. These differences were not significant.

Glasgow outcome score at 1 month was 4.96 for the BHC group and 4.85 for the TDC group. These differences in outcome were insignificant (p=0.235).

Mean MGS score was 1.65 for the BHC group and 1.95 for the TDC group. At discharge, the mean MGS score was 0.04 for the BHC arm and 0.21 for the TDC arm. At 1 month these were 0 for BHC and 0.19 for TDC group. These were not significant differences (p=0.47).

Only one patient failed to reach GCS at least 14 at discharge. This was a patient in the TDC arm who developed an operative site EDH and a craniectomy and tracheostomy had to be done for its management.

Radiological findings

SDH thickness and midline shift (MLS) was 19.8mm and 9.86mm respectively in the BHC arm. These were correspondingly 22.1mm and 10.5mm in the TDC arm. At discharge these were 8mm and 1.95m for BHC, and 8.13mm and 2.13mm for TDC (p=0.207 and 0.539 respectively). These were further reduced at 1 month to 0.45mm and 0mm for BHC group, and 2.47mm and 0mm for the TDC group (p=0.192 and 0.616 respectively). There was no significance in these differences.

Recurrence

There was 1 (2%) recurrence in the BHC arm and 4 (8.3%) in the TDC arm. This difference in recurrence rate was not statistically significant for both arms (p=0.307). The failure in BHC group was successfully treated by repeat BHC. Of 4 failures in TDC arm, one was immediately converted into an open craniectomy due to bleeding. Of the remaining three, two were successfully treated by redo TDC, while one required a burr hole for hematoma resolution. Thus of 48 patients in TDC arm, 42 were successfully treated by twist drill craniostomy (cure rate at 1 month = 88%). Of 52 patients in the BHC arm, 49 were successfully treated by burr hole craniostomy (cure rate at 1 month = 94%). These cure rates were not significantly different.

Complications

Complication were seen in 15% in BHC arm (in 49 patients who were followed up for 1 month) of which 6% was contributed by mild wound infections and the other 9% was due to sub dural hemorrhage or parenchymal contusion. Complication rate for the TDC arm was 15%, of which 2% was contributed by wound infection, 11% due to various types of hematoma formation and 2% due to meningitis. The complication rates in both arms were not significantly different (p=0.47). Iatrogenic parenchymal injury occurred in 2 patients in the BHC arm and 2 patients in the TDC arm. Incision size was average 6mm in the TDC arm and 38mm in the BHC arm.

Advantages of TDC over BHC

- Small, sutureless incision
- Bedside procedure under local anesthesia
- Inexpensive
- Time saving
- Cosmetically superior
- Can be converted into BHC

Poor outcome was seen in 2% patients, both in the TDC arm. One patient developed an EDH which was later operated. She had a KPS of 30, GOS 2 and MGS 3 at 1 month. The other patient was converted to BHC after 2 recurrences, developed a brain abscess and deteriorated to GCS 6/15. 1 month KPS was 30, GOS 2 and MGS 3. She was managed conservatively and improved to GCS 14 at 3 months.

DISCUSSION

CSDHs are one of the commonest neurosurgical problems seen in practice. The incidence is bound to rise primarily because of four factors: rising population of the elderly, increasing usage of antiplatelets and anti coagulants in patients of ischemic heart disease and occlusive cerebrovascular disease, wider availability of CT scanners and the resultant screening and the rising incidence of vehicle caused neurotrauma.

In this era of evidence based medicine there has been a genuine lack of well designed studies evaluating the various surgical procedures and there has been only one randomized study which has directly compared twist drill craniostomy with burr hole craniostomy[19]. In this study the authors compared randomly assigned 32 burr-hole operated patients with 38 twist-drill operated patients and concluded that both procedures appear similar. Other non randomized studies have also given similar conclusions[9, 17,20]. Most of these studies have correctly used the recurrence rate as the primary criteria with single unifying problem that the recurrence has never been adequately defined.

'Recurrence means symptomatic recurrence of the subdural hematoma at the site of previous surgery' is generally accepted as a definition but most studies have not defined what 'symptoms' define a recurrence and need for re-do surgery; indeed several studies have been published which followed arbitrary meanings of recurrence. Markwalder showed in his study that a persistent collection at the operated site is found in 78% cases upto 10 days after surgery, but this is no indication for surgery[7]. In our study also a persistent fluid and/ or air collection was a nearly universal phenomenon on the 5 day CT scan yet it rarely warranted re-do surgery as it was spontaneously reabsorbed usually within a month. Our low recurrence rates are a reflection of our fairly rigid criteria for defining recurrence in strict clinic-radiological terms.

Smely et al compared a prospective series of chronic subdural haematoma patients (n = 33) undergoing twist drill craniostomy with a historical control series of burr hole craniostomies (n = 33). Twist drill craniostomy significantly surpassed the results of the burr hole technique in lowering morbidity (0% v 18%), recurrence rate (18% v 39%), and duration of hospital stay (4.9 v 9.6 days) [21]. Gokmen et al, however, in their randomized study found no difference in clinical or radiological outcomes between the twist drill and burr-hole groups[19].

Weigel et al in their meta-analysis if 2003 found recurrence rates of 33% for twist drill and 12.8% for burr-hole, which they concluded was statistically significant[5]. Their paper however did not take into account the fact that the definition of recurrence was not clear in the studies they had analyzed and it is possible that several surgeons re-operated for even minor post operative subdural fluid collections which we are known to resolve spontaneously. They also showed that for recurrences after burr-hole, surgeons re-operate 85% cases by the same approach, while for recurrences after twist drill, 70% are re operated by the same approach and 25% by burr-hole.

We had 4 cases of delayed formation of contralateral CSDH, which later required surgery. Mori et al reported 3.6% contralateral CSDH occurrence [22].

Cost: the average cost of surgical consumables was Rs 680 per patient for the twist drill group versus Rs 2460 per patient for the burr hole group. This does not take into account the cost of anesthesaia, OT charges, surgeon and anesthetist fees, OT time, post operative room charges, among other things, which are significantly more for the patients undergoing burr-hole surgery.

Limitations: Twist drill craniostomy is unlikely to produce such good results when there is a relatively large organized subdural clot. Whether the results can be extrapolated to bilateral CSDHs is a matter of conjecture but appears likely to succeed. The role of irrigation and a post-operative drain in twist drill craniostomy surgery is still to be elucidated.

CONCLUSION

The recurrence rate of twist drill craniostomy with drain is not significantly different from that of burr hole craniostomy with drain for unilateral sub acute or chronic subdural hematomas ($p=0.307$). Other outcomes like GOS, KPS, complication rate, infection rate, mortality, cure rate, radiological resolution of hematoma and midline shift and MGS score were similar in both groups ($p>0.10$). Duration of surgery ($p<0.001$), cost of procedure ($p<0.05$), invasiveness (incision size) is significantly less in the twist drill group as compared to the burr-hole group ($p<0.05$). These factors and applicability at the bedside favor twist drill craniostomy as the procedure of first choice for treatment of sub acute or chronic subdural hematomas where the CT scan does not show an organized hyperdensity suggestive of a large clot.

Disclaimer: Most of the surgeries in the TDC arm were done using a patented cranial perforator introducer system similar to a twist drill, producing a craniostomy with an outer diameter of 4mm. Thus reproducibility of the results of this study are likely to vary marginally with the exact procedure adopted.

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