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Pros and cons of a minimally invasive percutaneous subdural drainage system for evacuation of chronic subdural hematoma under local anesthesia

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ABSTRACT

Objective: Chronic subdural hematoma (CSH) is a common neurosurgical disease among elderly population with concomitant degenerative neurological disorders. This is a retrospective series-control analysis of prospectively collected data, aiming to show advantages and indications of a minimally invasive, percutaneous drainage system for CSH.

Patients and methods: We retrospectively analyse the clinical and radiological data of a minimally invasive, percutaneous draining system (Integra ™) used in fifteen patients (Group A; mean age: 75.7) with CSH, and compare them with those obtained from two retrospective series of patients: the first one (Group B 15 patients, mean age 77.1) treated with standard, single-burr hole technique for subdural drainage under general anaesthesia; the second one (Group C 15 patients, mean age 76.4) treated with standard, single-burr hole technique for subdural drainage under local anaesthesia and mild sedation. All The percutaneous procedures (Group A) were performed under local anaesthesia.

Results: Mean follow-up was 10.9 (range 3–14), 18.2 (range 10–29) and 15.2 (range 8–28) months in Group A, B and C respectively. Three of 15 and in Group B experienced a worsening of pre-existing neurodegenerative disorders after general anaesthesia. One patient in group C suffering from Parkinson's disease experienced a worsening of gait disturbances. Post-operative CT scans were performed at 48 h and 21 days after the operation. An early post-operative CT-scan, obtained immediately after surgical procedure, was performed in all Group A patients. No differences in CSH evacuation were observed comparing the three groups. Two recurrent hematomas, one in group A and one in group B, required revision. Post-operative hospitalization was similar (5.1 vs 5.7 vs 5.6 days, respectively, in group A, B and C) but analgesics use was lower in Group A.

Conclusion: Pre-operative evaluation of radiological features of CSDHs is crucial in determining the right indication for a minimally invasive drainage. Minimally invasive treatments of CSH may reduce the use of anaesthetic drugs and worsening of pre-existing neurodegenerative disorders.

1. Introduction

Drainage of a chronic subdural haematoma (CSH) is a routine neurosurgical procedure often performed by younger neurosurgeons or residents [1]. The incidence of CSH is greater in the elderly population, as patients over-65 harbour a higher risk profile due either to co-morbidities or anti-coagulant/anti-platelet therapy [2,3]. Consequently, the growing percentage of aging population is associated with an increase in the incidence of CSH. Indications for surgery rely on imaging and neurological features, as well as on the overall patient's clinical assessment [4,5].

Despite the etiopathogenetic and clinical features of CSH have been widely investigated, there is no consensus on the best surgical option [6]. Several different techniques have been described over the years, aiming to optimally manage blood evacuation and reduce the recurrence rate as well as the invasiveness for patients [7,8]. Among less invasive drainage techniques for CSH, subdural tapping was proposed more than thirty years ago and, in the following years, was developed as an effective alternative to more aggressive procedures like single burr-hole, double burr-hole craniectomy or craniotomy [9].

Twist-drill craniostomy with closed-system draining catheter insertion gained appeal as bedside procedure [10–12]. However, none of the studies on the twist-drill technique did address clear indications for such percutaneous procedure, concluding that minimally invasive

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drainage could be empirically considered as a first attempt to manage CSH for patient in poor general conditions [11]. Recently, subdural evacuating port system (SEPS) has been commercialized and widely used as a minimally invasive treatment for CSH [13]. Several studies on such device have been published over the last ten years, highlighting the role of pre-operative CT-scan in identifying the best candidates for surgical treatment with SEPS [13–18]. Following encouraging clinical reports on the use of minimally invasive systems in CSH surgery, new systems for percutaneous evacuation of subdural haematomas have been developed.

We report our early experience on the use of the Integra™ minimally invasive subdural evacuation system in the surgical treatment of CSH under local anesthesia, comparing the data with two historical cohorts of patients, harbouring similar demographic features, who were treated with single, conventional burr-hole drainage under general anaesthesia and local anaesthesia respectively.

Patients' clinical and radiological outcome as well as complication and recurrence rates will be discussed. We will also try to identify the main clinical and radiological features to select the ideal candidate for this type of surgery, regardless of age and comorbidities.

2. Patients and methods

2.1. Study design and participants

This is retrospective series control analysis of prospectively collected data. The study was approved by local ethical committee and all enrolled patients and/or their relatives regularly signed a written informed consent before surgical procedures.

Fifteen patients (9 males) suffering from CSH, with a mean age of 75.7 years (range 62–93), were consecutively treated using the minimally invasive Integra™ subdural evacuation system (Group A). Two historical consecutive cohorts of patients treated with single hole craniectomy and drainage of subdural clots, was included as control groups. Group B included 15 patients (10 males) with a mean age of 77.1 years (range 57–87) treated with single hole and placement of a drainage (3.5 mm diameter) without suction under general anesthesia. Group C also included 15 patients (9 males) with a mean age of 76.4 (range 61–91) treated with single hole and placement of 3.5 mm drainage without suction under local anaesthesia and mild sedation No statistically significant differences were found comparing demographic data of both groups. Demographic data of patients included are summarized in Table 1.

2.2. Subdural evacuation system

The Integra™ minimally invasive subdural evacuation system has been conceived for drainage of subdural hygromas or CSH. The system has a low profile, small-tip catheter, which can be inserted through a 5-mm burr hole. The catheter has a metallic guide wire, which is useful to avoid crimping during insertion. Catheter is 25 cm in length and this allows a safe tunnelling through the skin. The most important feature of such system is the expandable tip of the catheter. After its insertion into the subdural space and removing of the guide wire, the catheter`s tip expands forming a small fenestrated umbrella, which anchors the catheter to the inner surface of the dura and avoids its inadvertent removal. The system kit is also provided with a 5-mm manual drill with adjustable stop and a Luer-lock adapter for connection of the catheter to the collection bag and/or vacuum pump. We prefer to apply a slight suction after connecting the catheter and to place the collection bag under the patient`s bed, in order to facilitate hematoma evacuation. Dural opening for insertion of the evacuation system should be minimal in order to avoid air aspiration within the subdural space. Differently from our standard surgical technique, we did not repeatedly irrigate with isotonic saline solution the subdural space until verifying complete clarification of the effluent fluid. Indeed, irrigation of the subdural space with isotonic solution through the catheter has been performed only to facilitate air evacuation, particularly in cases with difficult brain re-expansion due to pre-existing atrophy.

Table 1
Demographic characteristics of the three groups of patients.

	Group A	Group B	Group C
N. of patients	15	15	15
Mean age (range)	75.7 (62-93)	77.1 (57–87)	76.4 (61–91)
Male	9	10	9
Female	6	5	6

2.3. Clinical and radiologic assessment

Clinical and radiological data of the three groups were analysed. 13 of 15 patients in group A, 11 of 15 in group B and 12 of 15 patients in group C had pre-operative headache; focal neurological deficits (i.e. moderate aphasia, slight or moderate motor defects) were detected in 8, 11 and 10 patients in three groups, respectively. Five, seven and eight patients in group A, B and C respectively had a past medical history of neurodegenerative disorders. We evaluated the impact of pre-existing neurological conditions on clinical outcome pre- and post-operatively (one month after surgery) for all patients in three groups using the Unified Parkinson's Disease Rating Scale (UPDRS) part III and Mini Mental State Exam (MMSE). We compared length of post-operative hospitalization and use of analgesics between the three groups. We also evaluated the time of drain maintenance as well as the incidence of complications. Radiological evaluation was performed comparing the maximal thickness of the subdural collection detected on pre-operative and post-operative CT scans obtained at 48 h and 21 days after the operation, respectively. An early post-operative CT-scan, obtained just after ending the surgical procedure using a 8-slice small bore portable CT scan (CereTom® Neurologica, USA), was performed in all Group A patients to rule out complications related to the procedure. Reduction of midline shift under 5 mm, disappearance of hyperdensity areas within the subdural space and re-appearance of cortical subarachnoid spaces on the side of CSH were considered as complete evacuation. Conversely, the presence of ≥ 1 cm thick blood clot within the subdural space, associated to cortical compression on post-operative and/or first follow-up CT scan, was considered as incomplete evacuation.

3. Results

Mean follow-up was 10.9 (range 3–14), 18.2 (range 10–29) and 15.2 (range 8–28) months in group A, B and C respectively (Table 2). Neurological status improved in all but two patients (requiring revision surgery) in group A and B.

3.1. Use of analgesics

Three, six and seven patients in groups A, B and C respectively, complained of persistent headache after drains removal. Consequently,

Table 2
Clinical results of three cohorts.

	Group A	Group B	Group C
Post-operative addictional use of analgesic drugs	2.4 days (2 pts)	2.7 days (5 pts)	3.1 (7 pts)
Mean Post-operative hospitalization	5.1 days	5.7 days	5.6 days
Re-operation rate	1/15 (6.66%)	1/15 (6.66 %)	0/15 (0 %)
Mean follow-up	10.9 (3-14)	18.2 (10-29)	15.2 (8-28)

Table 3
Neurological outcomne.

	Group A		Group B		Group C	
Previous diagnosis of neuro-degenerative disease	5/15		7/15		8/15	
	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op
Headache	13/15	0/15	11/15	3/15	12/15	5/15
Neurological deficits	8/15	1/15	11/15	1/15	10/15	0/15
Mean UPDRS-part III	42.7	40.7	46.8	40.2	38.2	35.8
Mean MMSE	21.3	21.3	19.4	17.2	20.8	20.2

continuation of analgesic therapy beyond the standard protocol (Paracetamol 1000 mg three times daily, during 48 h after surgery) was required. Two patients in groups A received a mean of 2.4 more days of analgesic drugs, whereas five patients in group B required analgesics for 2.7 more days on average, and seven patients in group C for 3.1 more days on average (Table 2).

3.2. Clinical and radiological outcome

Mean post-operative hospitalization was 5.1, 5.7 and 5.6 days in three groups, respectively. Immediate post-operative CT scans in groups A patients ruled out complications related to the procedure, showing satisfactory drain placement and blood evacuation in all cases. Minimally invasive drainages as well as standard 3.5 mm diameter drainages were removed on the second or third post-operative day in all patients. Complications related to drainage removal were not observed in three groups of patients. Improvement of pre-operative neurological deficits as well as headache was documented in the majority of patients of three groups. Results of clinical and neurological outcome are summarized in Tables 2 and 3.

Post-operative CT scan performed 48 h after surgery showed the reduction in thicknesses of the subdural collections (Figs. 1–4): mean values reduced from 3.3 cm to 1.1 cm in group A, from 3.9 cm to 0.8 cm in group B and from 3.8 to 1.1 in group C. Such values further reduced to 0.6, 0.8 and 0.9 cm, respectively, on a late follow-up scan performed 21 days after surgery. According to the previously described radiological criteria, complete CSH evacuation was achieved in 12 of 15 patients in group A, 13 of 15 patients in group B and 12 of 15 patients in group C (Table 4). Consequently, 3 of 15, 2 of 15 and 3 of 15patients in groups A, B and C respectively, had incomplete evacuation documented

Fig. 1. Pre-operative CT scan of a 78-year-old gentleman suffering from large fronto-parietal subdural haematoma.

Fig. 2. Early post-operative CT scan shows the self-anchoring tip of evacuation system; the reappearance of cortical subarachnoid spaces documents the satisfactory evacuation of subdural collection. The thin hyperintense layer underneath the dura has been interpreted as the presence of parietal membrane of the hematoma, more evident after blood evacuation.

Fig. 3. Late CT scan depicts complete evacuation of hematoma.

on 48 h post-operative CT images. However, only two of such cases (one in group A, one in group B; reoperation rate 6.66%) required revision surgery (Table 2).

3.3. Management of recurrent CSHs

Surgical procedures for recurrent CSH were performed using standard single hole craniectomy and drainage of subdural clots only in one patient in group A and one in group B. Among patients with incomplete evacuation 2/3 cases in group A, 1/2 in group B and 3/3 in group C respectively, showed a recent bleeding as well as large compartmental membranes visible on pre-operative CT scans. Such radiological findings were not observed in the other cases harbouring complete CSH evacuation. In patients with incomplete evacuation who did not undergo re-operations (two in group A, one in group B and three in group C), prosecution of clinical and radiological follow-up was advised in

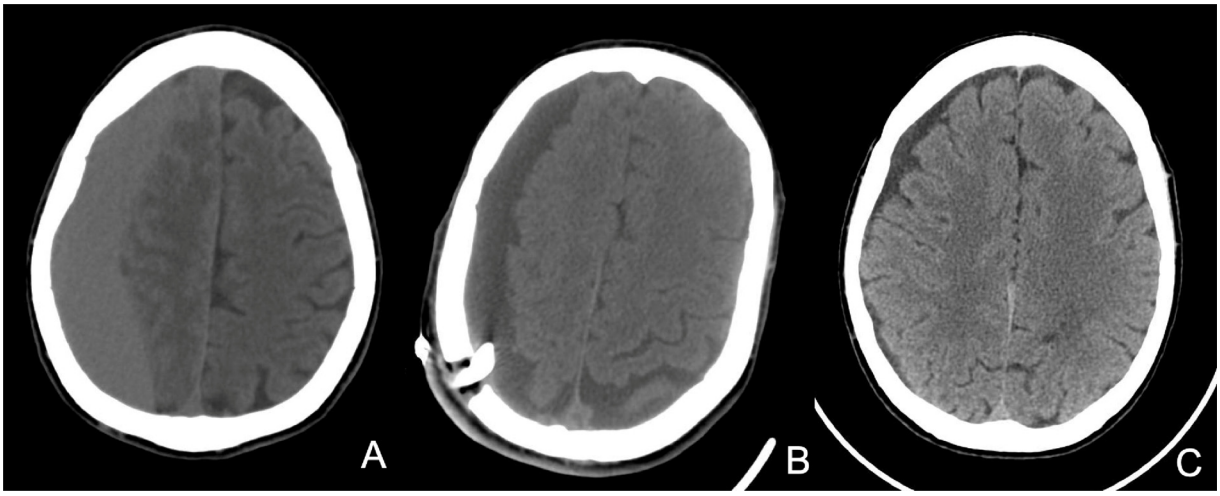

Fig. 4. Radiological evolution of a right chronic subdural hematoma treated with single burr-hole and drainage placement under general anaesthesia is shown (Group B): a 69-year-old lady presented with left hemiparesis. CT scan documented the presence of the hematoma causing severe compression of left hemisphere. Patient was treated under local anaesthesia with a single burr-hole, irrigation of subdural space and drainage placement. Early post-operative CT scan confirmed the evacuation of blood from the dural space and the initial re-expansion of brain parenchima (B). Late CT scan, performed 30 days after surgery, documented the absence of brain compression and displacement.

Table 4
Radiological outcome.

	Group A	Group B	Group C
Pre-operative subdural collection max thickness	3.3 cm	3.9 cm	3.8 cm
Post-operative subdural collection max thickness	1.1 cm	0.8 cm	1.1 cm
21 days FU subdural collection max thickness	0.6 cm	0.8 cm	0.9 cm
Complete evacuation	12 pts	13pts	12 pts

order to verify the progressive disappearance of residual fluid collections.

3.4. Outcome of patients with neurodegenerative disorders

Mean pre-operative UPDRS- part III was 42.7, 46.8 and 38.2 in groups A, B and C respectively. Post-operative UPDRS-part III, recorded at discharge was 40.7, 40.2 and 35.8. Variation of UPDRS-part III was statistically analysed with Student's *t*-test and it did not result statistically significant. Pre- and post-operative mean values of MMSE changed from 21.3 to 21.3 in group A, from 19.4 to 17.2 in group B and from 20.8 to 20.2 in group C. Also, variation of MMSE was not statistically significant (Student's *t*-test). (Table 3).

Among subgroups of patients with documented pre-existing neurodegenerative disorders (5/15 in group A, 7/15 in group B, 8/15 in group C), a worsening of cognitive or motor functions with a delayed recover of pre-operative status not related to incomplete CSH evacuation was observed in three group B patients. All these patients underwent general anaesthesia and the clinical worsening was defined as a decrease of 10 or more points in UPDRS-part III score or 3 or more points in MMSE score. Conversely, all group A and group C patients with neurological comorbidities underwent surgery with local anaesthesia and did not experience any worsening of their conditions.

Serious adverse events were not observed in either group. We did not report complications related to surgery (i.e.: infections, wound dehiscence, CSF leaks, etc) were experienced in any case. Significant pneumoencephalus with brain dislocation was never observed.

4. Discussion

4.1. Treatment options for CSH

The debate on best surgical treatment for CSH is an evergreen topic in Neurosurgery. The possibility to manage such pathological condition with a simple drainage has been proposed since 1932 [19]. Craniotomy, craniectomy, single burr hole, double burr hole and twist-drill hole have been proposed as alternative procedures. Several comparative studies appeared over last decades, investigating the different surgical techniques in order to establish a correct indication based on clinical and radiological features of CSH [6–8]. However, conclusive results were not obtained and the choice of surgical approach is still based on personal or institutional experience rather than on validated evidence. In 2010 one study reviewed the existing literature using decision analysis to find the most efficient surgical option to treat CSH [6]. The Authors concluded that the burr hole and drainage technique is the surgical procedure with the lowest recurrence rate and complications incidence. Similarly, to other comparative studies [8,12], they noticed that twist drill craniostomy showed similar results to the burr hole technique. Nevertheless, they also highlighted the absence of well-controlled large clinical series and the presence of confused data on morbidities and recurrences in the existing literature.

Minimally invasive treatment of CSH gained appeal over recent years, particularly after the introduction of the SEPS [13–18]. This system demonstrated effectiveness and safety, also as a bedside procedure useful in cases of patients in poor general conditions. In 2013 Neal et al. analysed the clinical data of 159 patients treated using SEPS for CSH, trying to identify possible factors predicting successful patient's outcome [18]. They concluded their analysis suggesting the non-use of SEPS in favour of alternative methods in cases with large proportion of recent bleedings and/or numerous septations within the subdural space. Kenning et al. previously performed a similar predictive analysis in a smaller cohort of patients [13]. They highlighted the importance of CT scan in identifying patients suitable for a minimally invasive procedure. Indeed, they concluded that hypodense haematomas may be more successfully managed by SEPS than mixed density blood collections. All studies on this device underlined the importance of such a minimally invasive procedure for the surgical management of CSH in elderly or compromised patients with severe comorbidities or chronically receiving antiplatelet or anticoagulant drugs.

4.2. Data interpretation

The subdural evacuation system used in the present series has been designed according to criteria for minimally invasive techniques: indeed, its features make it similar to SEPS. The uniqueness of this new

subdural evacuation system is the self-anchoring system, which is a particularly useful tool to avoid inadvertent displacement of the system. We did not encounter any difficulties during the device removal procedure, because the application of a moderate and controlled traction allows the folding of the small "umbrella-like" anchoring tip and its pull out.

We performed a comparative analysis between two different techniques to treat CSH, in order to assess the effectiveness of such minimally invasive tools. Data were prospectively collected. We did not document significant differences comparing clinical and radiological results in both groups and reoperation rate was the same (6.25%). The slight difference in the extent of evacuation as well as in mean value of residual collection thickness at late CT follow-up may be explained by the smaller caliber of the draining tube used in Group A treated with a minimally invasive technique. Arguably, a lower amount of subdural fluid was drained during 48 h after surgery, this being responsible for the different radiological, but clinically irrelevant, results at early follow-up. Interestingly, such difference was not present at 21-days control or at later follow-up visits performed in 7 patients with incomplete evacuation. Another interesting finding is the lack of significant radiological differences, despite two different techniques were used. Indeed, patients of group B and C underwent a standard burr-hole technique with copious irrigation in the subdural space, whereas no irrigation was used in group A.

Our clinical and radiological results are similar to those reported by studies on SEPS: we observed a similar reoperation rate (6.25%) but we did not report serious complications. We are aware of inherent limitations in the present study: our patient's surgical outcome's comparative analysis to the existing literature is limited by the small number of cases included. However, our data are prospectively collected differently from other study on SEPS, which are all retrospective [13,17,18]. The advantages of the percutaneous subdural drainage system are related to its very limited invasiveness. The procedure can be performed under local anaesthesia with a reduced or abolished use of opioids. This is particularly useful in patients with extrapyramidal syndromes and movement disorders, as demonstrated by clinical studies investigating the role of anaesthetic drugs in parkinsonian patients [19]. Similarly, patients suffering from dementia, Alzheimer's disease and/or cerebrovascular disorders may experience a worsening of their symptoms after surgery and general anaesthesia. The exact mechanism of such phenomenon is still debated as well as the precise contribution of anaesthetic drugs to the pathogenesis of these neurodegenerative disorders [20]. However, recent evidences suggest that anaesthesia may accelerate several neurological diseases, including tau pathologies [21,22]. Indeed, in the subgroups of patients with documented diagnosis of neurological disease we observed a worsening of cognitive and motor functions only in three Group B patients, operated under general anaesthesia. One of them, suffering from Parkinson's disease, experienced a worsening of rigidity requiring a re-modulation of pharmacological therapy. The comparative analysis between patients undergone minimally invasive subdural evacuation (group A) and patients treated with the standard procedure, under local anaesthesia (Group C), confirmed the benefits of avoiding general anaesthesia in elderly patients suffering from CSH. However, the analysis of clinical outcome suggested a moderate adjunctive benefit related to the minimally invasive drainage, likely due to shorter skin incision, smallburr hole, reduced use of analgesic drugs and shorter hospitalization. We also hypothesized that these findings may be explained by the self-anchoring mechanism, which could create a reduced mechanical stress on inner dural layer in comparison to a standard drainage involving a more extended portion of dura mater.

A critical review of all cases' post-operative CT scans suggested that the best indication for a percutaneous system is a fluid collection without radiological evidences of compartmental membranes inside the hematoma or recent bleedings. This observation is consistent with previously cited studies on predictors of success for minimally invasive drainage of CSH [13,18].

The minimal invasiveness of such system, documented by lower use of analgesic drugs in Group A, allowed patients' rapid clinical recovery, with short post-operative hospitalization. This is a clear advantage, allowing a quicker return to normal daily activities and an early rehabilitation in elderly patients.

4.3. Limitations

This study has some limitations related to the small size of the sample and the lack of statistical analysis. However, the aim of this clinical report is to validate the feasibility, the safety and the effectiveness of the minimally invasive treatment of CSHs using Integra™ self-anchoring evacuation system, trying to identify the best candidate for such surgical options. We are aware that larger studies and cost-effectiveness analyses are required to better assess the advantages of using of such device in CSH surgery.

5. Conclusions

Our early experience with the Integra™ minimally invasive subdural evacuation system demonstrated that such tool appears to be safe and effective in the surgical treatment of CSH. Pre-operative evaluation of radiological features of CSDHs is crucial in determining the right indication for a minimally invasive drainage procedure. Further studies on larger cohorts are required to confirm the advantages as well as the pitfalls of such system.

This clinical research has been authorized by local ethical committee.

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