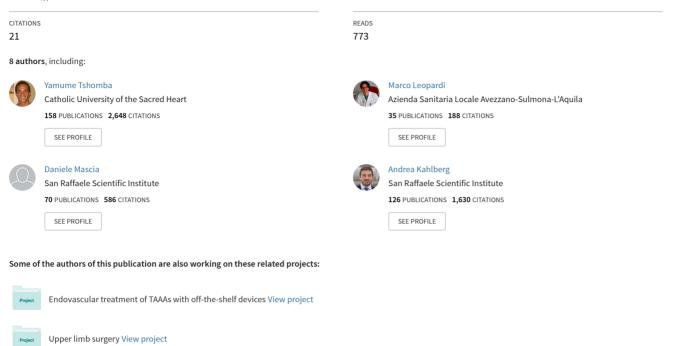
Automated pressure-controlled cerebrospinal fluid drainage during open thoracoabdominal aortic aneurysm repair

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Automated pressure-controlled cerebrospinal fluid drainage during open thoracoabdominal aortic aneurysm repair

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ABSTRACT

Objective: Perioperative cerebrospinal fluid (CSF) drainage is a well-established technique for spinal cord protection during thoracoabdominal aortic aneurysm (TAAA) open repair and is usually performed using dripping chamber-based systems. A new automated device for controlled and continuous CSF drainage, designed to maintain CSF pressure around the desired set values, thus avoiding unnecessary drainage, is currently available. The aim of our study was to determine whether the use of the new LiquoGuard automated device (Möller Medical GmbH, Fulda, Germany) during TAAA open repair was safe and effective in maintaining the desired CSF pressure values and whether the incidence of complications was reduced compared with a standard catheter connected to a dripping chamber.

Methods: Data of patients who underwent surgical TAAA open repair using perioperative CSF drainage at our institution between October 2012 and October 2014 were recorded. The difference in CSF pressure values between patients who underwent CSF drainage with a conventional dripping chamber-based system (manual group) and patients who underwent CSF drainage with the LiquoGuard (automated group) was measured at the beginning of the intervention (T1), 15 minutes after aortic cross-clamping (T2), just before unclamping (T3), at the end of surgery (T4), and 4 hours after the end of surgery (T5). The choice of the draining systems was randomly alternated with one-to-one rate until the last six patients consecutively treated with LiquoGuard were enrolled. Primary outcomes were occurrence of spinal cord ischemia, intracranial hemorrhage, postdural puncture headache, and in-hospital mortality.

Results: The study included 152 patients who underwent open surgical TAAA repair during the study period: 73 patients underwent CSF drainage with the traditional system and 79 with LiquoGuard. The CSF pressure values at TI and T5 were not considerably different in the two groups. By repeated-measures analysis of variance, a significant upward trend of perioperative CSF pressure was observed in the automated group at T2, T3, and T4 (group \times time interaction = $F_{3.66}$; P < .001). No difference was reported in the occurrence of spinal cord ischemia, intracranial hemorrhage, or mortality. The LiquoGuard group reported significantly reduced postdural puncture headache (3.3% vs 16.9%; P = .01).

Conclusions: Perioperative use of LiquoGuard during TAAA open repair was safe and effective. Despite slightly higher intraoperative CSF pressures, the rate of spinal cord ischemia did not increase in the LiquoGuard group, and postdural puncture headache significantly decreased. (J Vasc Surg 2017; 1-8.)

Spinal cord injury in patients who undergo thoracoabdominal aortic aneurysm (TAAA) open repair may affect perioperative and long-term outcomes because of multiple and severe medical complications directly related to the neurologic damage. Paraplegia and paraparesis have also noteworthy social and financial aspects, making all of the new methods focused on improvement in spinal cord protection remarkable.¹

Cerebrospinal fluid (CSF) drainage represents an evidence-based protective adjunct that has been described in randomized controlled trials and meta-analyses.²⁻⁶ CSF drainage pressure is usually monitored during surgery and in the postoperative period by medical and paramedical staff. The measurement and subsequent drainage are traditionally performed manually by gravity using dripping chamber-based systems.

The LiquoGuard (Möller Medical GmbH, Fulda, Germany) is a new device for controlled, continuous CSF drainage designed to maintain CSF pressure around the desired set values, thus avoiding unnecessary drainage and allowing simultaneous monitoring of CSF pressure and active drainage. Few publications describe the use of LiquoGuard in patients undergoing open TAAA repair, and fewer still focus on comparison with traditional drip chamber-based systems. The in this report we describe our contemporary experience with the use of LiquoGuard during TAAA open repair and compare the outcomes with a traditional manual system.

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METHODS

This retrospective study followed the principles outlined in the Declaration of Helsinki and used only information obtained from the review of medical records. Patients gave consent for the anonymous collection of

Author conflict of interest: Y.T. was lecturer at symposia hosted by Tekmed Instruments S.P.A.

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their data on the standard consent sheet provided by our institution. Data collection was in conformity with the Italian laws on privacy (Art. 20-21, DL 196/2003) published in the Official Journal, Vol 190, August 14, 2004, which explicitly exempts the need for ethical approval for the use of anonymous data.

We keep a database of all patients undergoing TAAA repair in our institution to observe their follow-up. Data of consecutive patients who underwent surgical TAAA open repair with CSF drainage between October 2012 and October 2014 at our institution were collected.

CSF drainage pressures were recorded at the beginning of the intervention (TI), 15 minutes after aortic cross-clamping (T2), just before unclamping (T3), at the end of surgery (T4), and 4 hours after the end of surgery (T5). The difference in pressure values of CSF between patients who underwent CSF drainage with a conventional dripping chamber-based system and patients who underwent CSF drainage with the LiquoGuard was measured.

Primary outcomes were incidence of spinal cord ischemia, intracranial hemorrhage, postdural puncture headache, and in-hospital mortality. Postdural puncture headache was defined as headache occurring ≤5 days of a lumbar puncture accompanied by neck stiffness or subjective hearing symptoms, or both, and spontaneously remittent ≤2 weeks, according to the International Classification of Headache Disorders (ICHD), 3rd edition (beta version).¹⁰ The severity of headache was graded as I (mild), II (moderate), or III (severe) using a grading system based on the visual analog scale (associated with a functional rating).¹¹

Before general anesthesia was induced, an epidural catheter was usually placed at the T7-T8 level by using a loss-of-resistance technique, and test dosing was performed with 40 mg of 2% lidocaine. General anesthesia was induced with propofol (2 mg/kg), fentanyl (1-2 μ g/kg), and cisatracurium (0.15-0.2 mg/kg). For maintenance of general anesthesia, desflurane, maintained at 1 to 1.5 minimum alveolar concentration, and repetitive fentanyl boluses were administered. A left double-lumen endotracheal tube was positioned under fiberoptic guidance.

Catheter insertion for the planned CSF drainage was performed after anesthesia was induced. With patients in lateral decubitus, one 18-gauge silicone catheter was introduced into the subarachnoid space at the L2-L3 or L3-L4 level and advanced ~5 cm in the lumbar subarachnoidal space to allow CSF pressure monitoring and drainage. Firm catheter fixation was performed with a subcutaneous anchoring in all patients. CSF drainage was managed perioperatively manually (manual group) with a traditional drip chamber-based catheter or automatically (automated group) with a catheter connected to the LiquoGuard device, which allows active pressure transducer-based drainage using a peristaltic pump (Fig 1). Finally, the catheter was

connected to the pressure transducer (manual group) or to the LiquoGuard (automated group). The choice of the draining system during the study period was arbitrary: the two systems were randomly alternated with one-to-one rate until the last six patients consecutively treated with LiquoGuard were enrolled.

At the end of surgery, patients were transferred to the intensive care unit (ICU) for postoperative monitoring. Sedation was discontinued after body temperature of ≥36°C was reached and hemodynamic stability were achieved. Spinal cord function was clinically evaluated at awakening and classified by an independent neurologist according to the Tarlov scoring sysytem. Postoperative epidural analgesia with 0.2% ropivacaine (99 mL) plus sufentanil (50 µg/l mL at 4-6 mL/h) was started after assessment of neurologic status and was discontinued in case of neurologic deficiencies.

The CSF pressure was monitored during the intervention and for 72 hours postoperatively with both the systems. In asymptomatic patients, CSF was drained to maintain a CSF pressure of <10 mm Hg with a maximum flow rate of 20 mL/h. In symptomatic patients, this threshold was lowered to 5 mm Hg, without any limit of drained volume in the manual group. To avoid spinal cord hypoperfusion, we prefer to maintain a perioperative mean arterial pressure of >90 mm Hg, eventually with catecholamines use, as we described in a prior experience.¹³

Manual group. The manual gravity-based system was situated beside the patient hung to a standard pole. Our institution currently uses the Becker External Drainage system (Medtronic, Santa Rosa, Calif), which incorporates a transducer that receives the CSF tubing and measures the relative pressure compared with atmospheric pressure. It needs to be adapted in height, and a drip chamber mounted below the transducer collects the drained CSF. This system is routinely used and did not change over the time.

The CSF was drained continuously in operating room after catheter insertion, and was manually stopped for 10 minutes if drainage was faster than 20 mL/h. In those cases, CSF pressure was measured again after a 10-minute interval, and if <5 mm Hg CSF, drainage was stopped until a pressure of >5 mm Hg was obtained.

During ICU and ward observation, CSF pressure was monitored for every 4 hours for 72 postoperative hours and drained for 15 minutes only if CSF pressure was >10 mm Hg. In asymptomatic patients, in case of pressure still >10 mm Hg after 15 minutes of drainage, another other 15 minutes of drainage was performed until a pressure of <10 mm Hg was obtained to a limit of 15 mL/h of drainage.

During measurement and drainage, patients were kept still and supine to avoid biases of measurement caused by incorrect patient position and movements. After CSF Journal of Vascular Surgery Volume ■, Number ■

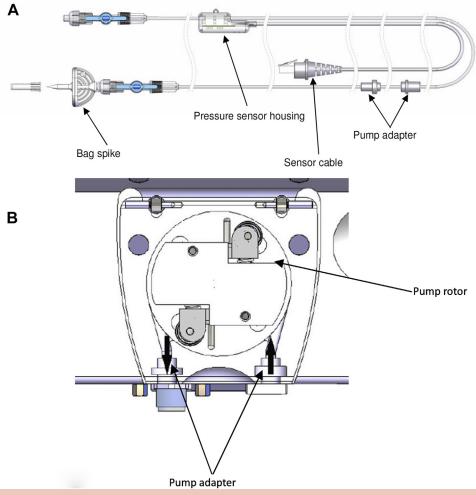


Fig 1. A, LiquoGuard Lumbar (Möller Medical GmbH, Fulda, Germany) drain tube set. B, Pump detail.

pressure monitoring or drainage, or both, the catheter was closed again and pressure reassessed after 4 hours. In case of neurologic symptoms, CSF was drained manually by gravity to maintain a pressure of <5 mm

manually by gravity to maintain a pressure of <5 mm Hg, without any limit of drained volume but always under a careful check of absence of bloody CSF.

Computed tomography or magnetic resonance imaging, or a neurophysiologic assessment, or both, were performed if no neurologic improvement in response to arterial pressure augmentation and CSF drainage was shown.

Automated group. Drainage in the automated group was performed by connecting the lumbar catheter to the LiquoGuard system, which simultaneously allows continuous monitoring of CSF pressure and an active pressure-controlled drainage. In the patients of the automated group, CSF was drained automatically based on a preset of a maximum CSF pressure of 10 mm Hg. At this level, the pump automatically started draining until the pressure was lowered to <10 mm Hg. The maximum CSF drainage rate set with the LiquoGuard system is 20 mL/h.

In case of neurologic symptoms in the ICU and in the ward, in our protocol CSF was set at a maximum CSF pressure of 5 mm Hg without any limit of drained volume.

Statistical analysis. Continuous variables are presented as mean \pm standard deviation. Variables with nonnormal distributions are presented as median (interquartile range), and discrete variables are reported as number (%) of patients. Analyses were performed using Stata 11.0 software (StataCorp LP, College Station, Tex). We used the Student t-test for comparison between groups, and the χ^2 test was used for comparison between categoric variables.

RESULTS

Data were collected for 152 consecutive patients who underwent open surgical TAAA repair. Among these, 73 patients underwent CSF drainage with the Becker External Drainage and Monitoring System and 79 with the LiquoGuard system. Demographics, anthropometric variables, preoperative clinical characteristics, prior aortic surgery, and the extension of aortic surgery are described in Table I. Data and TAAA extent were similar between

Table I. Anthropometric variables and preoperative data^a

Variables	Total patients (N = 152)	Manual drip-chamber drainage group (n $=$ 73)	LiquoGuard ^b group (n = 7 9)	<i>P</i> value
Age, years	66.5 ± 9.0	66.5 ± 9.4	66.7 ± 5.3	.88
Weight, kg	75 ± 13.4	75 ± 13.7	71 ± 12.3	.10
Creatinine level, mg/dL	1.1 ± 0.47	1.1 ± 0.47	1.2 ± 0.49	.27
Hypertension	130 (85.5)	62 (84.9)	68 (86.1)	.84
Diabetes	35 (23.0)	19 (26.0)	16 (20.2)	.39
History of smoking	135 (88.8)	62 (86.9)	73 (92.4)	.14
Coronary artery disease	47 (30.9)	27 (36.9)	20 (25.3)	.11
Prior aortic repair	15 (9.9)	7 (9.6)	8 (10.1)	.91
TAAA extent ^c				
I	9 (5.9)	4 (5.5)	5 (6.3)	.82
II	51 (33.5)	20 (27.4)	31 (39.2)	.12
III	42 (27.6)	24 (32.9)	18 (22.8)	.16
IV	49 (32.2)	25 (34.2)	24 (30.4)	.61
V	1 (0.7)	O (O)	1 (1.3)	.33

TAAA, Thoracoabdominal aortic aneurysm.

 $^{
m a}$ Continuous data are presented as mean \pm standard deviation and categoric data as number (%).

^bMöller Medical GmbH, Fulda, Germany.

^cAccording to the Crawford-Safi TAAA classification.

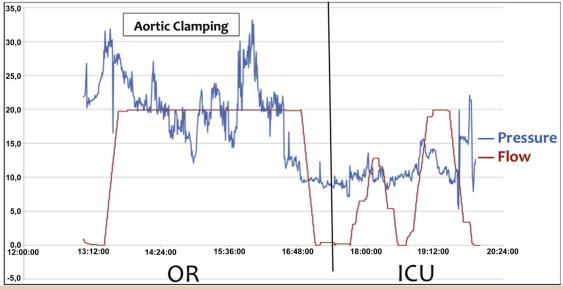


Fig 2. Diagram shows simultaneous pressure measurement and drainage flow with the LiquoGuard system (Möller Medical GmbH, Fulda, Germany) in the operating room (*OR*) and in the intensive care unit (*ICU*) stay. Of note, the increased pressure during aortic clamping with automatic start of drainage at a maximum flow of 20 mL/h until the drop of cerebrospinal fluid (CSF) is <10 mm Hg.

groups. The risk factors for spinal cord ischemia were equally distributed in the two groups considering both anatomic TAAA extent and previous sacrifice of spinal segmental arteries.

During surgical repair, we performed a left heart bypass with distal aortic perfusion in type I to III TAAAs and in seven patients (14.3%) with type IV TAAAs.

CSF drainage measurement and drainage was achieved in all patients in both groups in the operating

room, ICU, and in the ward for 72 hours (Figs 2 and 3). Mean pressure values of CSF at Π and T5 were not considerably different in the two groups.

By repeated-measures analysis of variance, a significant upward trend of perioperative CSF pressure was observed in the automated group at T2, T3, and T4 (group \times time interaction = $F_{3.66}$; P < .001; Fig 4).

In the postoperative period, there was no difference between the manual group and automated group,

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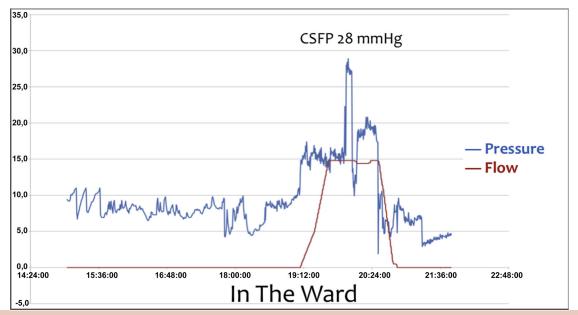


Fig 3. Diagram shows the LiquoGuard system (Möller Medical GmbH, Fulda, Germany) use in the ward; of note, neither unnecessary drainage nor manipulation when cerebrospinal fluid pressure (*CSFP*) was <10 mm Hg.

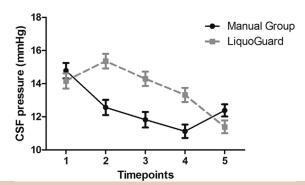


Fig 4. Perioperative variations of cerebrospinal fluid (*CSF*) pressure values from the preoperative value up to 4 hours after the end of surgery. Comparison between the automated and manual groups was made using a general linear model repeated-measures analysis of variance. Within-factor effect (time): $F_{52,34}$, P < .001; between-factor effect (group): $F_{2,64}$, P = .11; group-time interaction: $F_{3,66}$, P < .001.

respectively, for paraparesis (10.9% vs 7.5%; P=.47) and paraplegia (6.8% vs 6.3%; P=.89). We observed four cases of intracranial hemorrhage in the manual group. No CSF drainage complications, bloody drainage, or catheter dislocations occurred.

The mean amount of CSF drainage was 280 mL in automatic group patients and 350 mL in manual group patients (P = .12).

We observed postoperative hypotension in 52 patients, which was symptomatic for transient paraparesis in 18 patients, and completely regressed in all patients with the treatment of hypotension. Among those patients, 36 (69.2%) needed systemic vasopressors with

catecholamines. Significantly reduced postdural puncture headache (3.3% vs 16.9%; P=.01) was reported in the LiquoGuard group (Table II). No spinal hematoma, meningitis, or spinal abscesses were observed. In the cohort of patients analyzed, we did not observe any difference in surgical and CSF drainage complications between the two groups in the follow-up.

DISCUSSION

Spinal cord and its fluids circulation are confined in a nonexpandable compartment, with a production of 0.2 to 0.7 mL/min and 400 to 600 mL/24 hours, and in normal conditions, CSF pressure is 10 to 15 mm Hg. Spinal cord perfusion pressure is represented by the difference between spinal mean arterial pressure, which is usually 70 mm Hg.¹⁴⁻¹⁷ and CSF pressure.^{18,19} When CSF pressure exceeds spinal venous pressure, a "critical closing pressure" is reached, causing the veins to collapse independently of arterial pressure.

Systematic reviews, randomized and nonrandomized trials, and cohort studies previously showed that CSF drainage is an effective procedure to prevent paraplegia when this adjunct is used in centers with considerable experience in the management of TAAAs.^{20,21}

However, along with spinal cord perfusion protection, this technique is also associated with severe complications, such as intracranial bleeding, presenting both with subdural and intraparenchymal hemorrhage. Intracranial hemorrhage may result from traction of the dural veins due to their caudal displacement as well as from the intracranial hypotension, which leads to venous engorgement, especially at the level of dural venous

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Table II. Cross-clamp duration and cerebrospinal fluid (CSF) pressure in the overall population, in the Becker External Drainage group, and in the LiquoGuard group^a

Variables ^b	Total patients $(N = 152)$	Manual drip-chamber drainage group (n = 73)	LiquoGuard group (n = 79)	<i>P</i> value
Cross-clamp duration, minutes	42 ± 15.4	42 ± 14.2	44 ± 22.7	.54
CSF pressure, mm HG				
П	15 ± 7.4	15 ± 7.5	14 ± 7.4	.48
T2	14 ± 6.6	13 ± 6.8	15 ± 8.8	.02
Т3	13 ± 4.9	12 ± 4.7	14 ± 3.2	.02
T4	12 ± 4.3	11 ± 4.1	13 ± 4.2	.03
T5	11 ± 4.1	12 ± 4.2	11 ± 4.2	.14
Hypotension	52 (34.2)	23 (31.5)	29 (36.7)	.49
Paraparesis	14 (9.2)	8 (10.9)	6 (7.5)	.47
Paraplegia	10 (6.6)	5 (6.8)	5 (6.3)	.89
Intracranial hemorrhage	4 (2.6)	4 (5.4)	0	.03
Postdural puncture headache				
Grade II	8 (5.3)	5 (6.8)	3 (3.8)	.39
Grade III	7 (4.6)	6 (8.2)	1 (1.3)	.04
Overall	15 (9.9)	11 (15.1)	4 (5.1)	.03
Thirty-day mortality	9 (5.9)	6 (8.2)	3 (3.8)	.24

TI, Beginning of the intervention; T2, 15 minutes after aortic cross-clamping; T3, just before unclamping; T4, at the end of surgery; T5, 4 hours after the end of surgery.

 $^{\mathrm{a}}$ Continuous data are presented as mean \pm standard deviation and categoric data as number (%).

^bMöller Medical GmbH, Fulda, Germany.

sinuses. In some reported series, intracranial bleeding is reported with a rate between 0.45% and 2.8% and is more often observed with a large volume of CSF drainage.^{22,23}

Several devices are currently found in the market to support CSF management. The most common systems for CSF drainage use a gravity-based drip chamber, and they have many practical disadvantages. One of the most remarkable drawbacks of these systems is the impossibility of a simultaneous drainage and pressure measurement. Also, there are a multitude of possible handling mistakes, related to concerns of safety, sterility, human error, and clinical personnel workload, which may lead to dangerous over/under drainage and catheter contamination. Those are mainly represented by congestion of the air filter or tubing, incorrect height alignment of the system and dripping chamber, incorrect connection of tubing system, and fitting and positions of the stopcocks. Repeated manipulation, which is necessary when manual systems are used, augments contamination risk and may also increase the risk of catheter infection and meningitis. 9,23

An automatic drainage system allows a CSF drainage system to activate according to CSF pressure changes, which incorporates a pump to drain CSF while a sensor acts as a control variable for the operation of the pump. The pressure sensor, along the tubing, continuously measures the pressure in the CSF catheter, and the volume of CSF pumped out is also continuously measured. The CSF

automatic drainage system has the advantage that the CSF is drained not simply on the basis of the excess pressure but is actively pumped out in a controlled manner. Furthermore, it does not require any manipulation, and the time required to measure the CSF pressure is the few seconds needed to read the pressure values on the screen compared with the mean of 15 minutes needed with manual systems. Several parameters can be regulated with the automated system: hourly drainage speed, maximum and minimum CSF pressure, and maximum amount to be drained per hour. It must be stressed that a bailout procedure in case of insufficient draining is always allowed by shifting to manual drainage.

Automated systems even allow the patient to change position in the bed, and to move freely because the transducer is set at the first connection and then works with a closed circuit. This avoids the forced supine position that is required during manual measurements.

Headache is another described complication after CSF drainage, found in 0.2% to 9.7% of patients, which is mainly related to reduced tension on the sensory receptors of the dural sinuses. 7.23.24 With intracranial hypotension, it is thought that caudal displacement of the brain may lead to stretching of sensory receptors in the dural sinuses, leading to spinal headaches. We usually treated patients with postdural puncture headache with paracetamol and caffeine, obtaining a total or partial remission of symptoms between 4 and 8 days after surgery.

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Patients undergoing TAAA open repair need to move early, practice physical therapy, and stay seated instead lying in bed to improve respiratory functions. A potentially harmful delay of rehabilitation activities of the patients occurs if they are forced to stay in bed for headache therapy. Then because puncture headache may complicate the crucial early postoperative days of these patients, reducing this complication may be useful even in order to allow earlier patient mobilization and better compliance, and both of these have the potential to improve patient outcomes. Although puncture headache may derive from leakage from the puncture site that is not device-dependent, we never observed significant CSF leakage in our patients who complained of postlumber puncture headache.

Few studies have previously reported results with the use of automated CSF draining systems, 7-9 and only one among them described CSF drainage during aortic repair. Kotelis et al 7 describes a median CSF drained volume of 714 mL, a spinal cord ischemia rate of 3%, and other complications, including 1 fatal intracranial hemorrhage, 3 episodes of bloody CSF, 3 persistent CSF leaks requiring an epidural blood patch, and 3 postlumbar puncture headaches, with a 16-month mortality of 3%. To the best of our knowledge, this current report presents the first comparative study between an automated and a manual system.

CONCLUSIONS

Perioperative use of the LiquoGuard during TAAA open repair was safe and effective. Compared with a drip chamber-based system, we observed no difference in spinal cord ischemia, intracranial hemorrhage, and mortality between the two groups in our series. Slightly higher intraoperative CSF pressures were reported with the LiquoGuard at some recording times, together with reduced postdural puncture headache.

Larger cohorts of patients, prospective studies, randomization, and a deeper knowledge of the best protocol to standardize CSF drainage, together with a correlation of the CSF pressure values with patient hemodynamic status and CSF drained volumes, are required to confirm the results of our study.

Careful assessment of new technology in CSF drainage is especially important for the future perspectives when endovascular TAAA repair, even with percutaneous approaches, will increase, and CSF drainage systems allowing the patients to move freely in the first postoperative hours after the procedure will be strongly appreciated.

AUTHOR CONTRIBUTIONS

Conception and design: YT, ML, GM, RC Analysis and interpretation: YT, ML Data collection: ML, DM, AK, AC, SM

Writing the article: ML

Critical revision of the article: YT, DM, AK, AC, SM, GM, RC

Final approval of the article: YT, ML, DM, AK, AC, SM, GM, RC Statistical analysis: ML

Obtained funding: Not applicable

Overall responsibility: YT

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