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Dural splitting has similar therapeutic efficacy with less complications, shorter operative and hospitalization times when compared to duraplasty in chiari type-I malformation

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ABSTRACT

Aim: A standard surgical technique has not been developed for Chiari Type-1 malformation. Recently, dural-splitting has also been introduced in addition to duraplasty. We aimed to determine both surgical techniques' advantages/disadvantages clinically and radiologically.

Material and Method: We retrospectively evaluated 28 patients' data with Chiari Type-I malformation and operated at the Neurosurgery Department of Bülent Ecevit University between January 2014 and April 2018. We retrieved demographic characteristics, symptoms, physical/neurological findings, preoperative/postoperative imaging data/measurements, Visual Analog Scale, Chicago Chiari Outcome Scale, Neck Disability Index, Neurological Scoring System, and the modified Japanese Orthopedic Association scores, operation and hospitalization times, and complications from the automation system.

Results: Patients' mean age was 38.5±13.0 years, and female/male ratio was 2.1/1. Syringomyelia was present in half of all cases. Mean tonsil herniation length was 11.64±4 mm, and mean tonsillo-dural distance was 4.18±1.7 mm. There were no significant relationships between tonsil herniation length and syringomyelia, and between tonsillo-dural distance and clinical improvement. Posterior fossa decompression was initially performed in all patients. Then, in 17 patients, duraplasty was performed. In 11 patients, dural-splitting was used. No significant differences were determined between duraplasty and dural-splitting regarding Visual Analog Scale, Chicago Chiari Outcome Scale, Neck Disability Index, Neurological Scoring System, and the modified Japanese Orthopedic Association scores. Significant differences were present, favoring dural-splitting regarding operation time, hospital stay, and complication rates.

Conclusion: Posterior fossa decompression/duraplasty is an effective surgical technique to treat Chiari Type-I malformation. Posterior fossa decompression/dural-splitting is an optimal surgical alternative with a lower complication rate, shorter operation time, and hospitalization period.

Keywords: Chiari type-I malformation, duraplasty, dural splitting

INTRODUCTION

Chiari malformations are congenital or acquired malformations associated with herniation of the cerebellum, brainstem, and fourth ventricle. Even though Cleland had first described and named them as "primary cerebellar ectopia," Hans Chiari reported and classified the first cases diagnosed with Chiari malformation in 1891 (1). Among the four subtypes of Chiari malformations, the first three types involve various rhombencephalon herniation severity, Chiari Type-I is the most common, and Type-IV is a malformation involving cerebellar hypoplasia/aplasia (2). Accompanying syringomyelia with an incidence of 30-70% and other anomalies of mainly the cervical region may be observed (3, 4).

Chiari Type-I malformation is more common in females than males and usually becomes symptomatic in the third and fourth decades. Since the Chiari Type-I malformation initially manifests itself with nonspecific suboccipital, shoulder, and extremity pain and numbness, it is difficult to diagnose (3, 5). Cerebellar tonsillar herniation of five mm or more in Magnetic Resonance Imaging (MRI) is significant for definitive diagnosis (5).

Since symptoms develop in Chiari Type-I malformation because of craniovertebral junction compression and impaired cerebrospinal fluid (CCF) circulation dynamics, surgical treatment aims to resolve the existing compression and rearrange the impaired CCF dynamics (4). The most commonly preferred method is foramen magnum

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decompression with duraplasti (6). In recent years, foramen magnum decompression with dural splitting has been introduced to neurosurgical practice (7). Today, both methods take place in the armamentarium of neurosurgeons.

This study aimed to identify the improvement rates of patients' signs and symptoms, investigate, and compare the two surgical methods' treatment results, determine surgical methods' superior aspects and effects on patient outcome, and create alternatives regarding surgical technique preference in appropriate patients.

MATERIAL AND METHOD

Following approval by Ethics Committee for Clinical Research in Zonguldak Bülent Ecevit University (Date: 19.12.2019, Deision No: 2018-244-19/12) for retrospective investigation of patient data and imaging results, the medical records and radiological images of the patients who had undergone surgery with the diagnosis of Chiari Type-I malformation at Zonguldak Bülent Ecevit University Department of Neurosurgery between January 2014 and April 2018 were retrospectively investigated. All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Patients who had undergone surgery with the diagnosis of Chiari Type-I malformation were included in the study. Patients under 18 years of age, patients who had undergone surgery for Chiari Type-I malformation in another clinic, and patients who had been conservatively treated and followed up were excluded from the study.

The demographic characteristics such as age and gender, symptoms at admission, physical and neurological examination findings, preoperative and postoperative radiological imaging data and measurements, the scores and results of the scales preoperatively or postoperatively such as the visual analog scale (VAS), Chicago Chiari Outcome Scale, Neck Disability Index, Neurological Scoring System, and the modified Japanese Orthopedic Association (JOA) scores, operation and hospitalization durations, and complications were retrieved from the automation system and recorded. Besides, when required, measurements such as the herniated tonsil's length and the tonsillo-dural distance were made on the patients' radiological images and recorded. In our clinic, patients are called for routine control in the 1st, 6th and 12th months. In patients in whom syringomyelia was present, the syrinx cavity/medulla ratio was measured on the preoperative and postoperative 6th and 12th months and recorded. Stabilization was performed on a patient in the duraplasty group whom basilar invagination and Klippel Feil syndrome.

Statistical Analysis

Statistical analysis of the study was performed using the SPSS (Statistical Package for the Social Sciences-IBM), v.19 software package. Descriptive statistics of the study's continuous variables were presented as mean, standard deviation, median, and minimum-maximum values, whereas categorical variables were shown as frequency and percentage. The compliance of continuous variables to normal distribution was investigated by the Shapiro-Wilk test. The Mann-Whitney U test was used for variables' 2-group comparisons not showing a normal distribution, whereas the independent samples t-test was used for normally distributed variables' 2-group comparisons. The Pearson, Yates, and Fisher chi-square tests were used for inter-group comparisons regarding qualitative variables. The relationships between continuous variables were investigated using the Spearman and Pearson correlation analysis methods. A p value below 0.05 was considered statistically significant in the study's all statistical analyzes. The study's statistical analyzes were performed with the support of Biostatistics Department in Bülent Ecevit University, Medical Faculty.

RESULTS

Demographics and Constitution of the Groups: Twenty-eight patients were determined to have the inclusion criteria to the study. The patients' chart reviews revealed that, following posterior fossa decompression, the dura mater was opened and a widening duraplasty was performed in 17 patients, and these patients made up the Duraplasty Group. Chart reviews also revealed that, in 11 patients, the thick bands over the dura mater were peeled off together with the external layer of dura mater, and microincisions were performed on the internal duramater layer; these patients made up the Dural Splitting Group.

Age and Gender: The mean age of the entire patient group was 41.39±13.12 years, and there was no statistically significant difference between the two groups regarding age (p>0.05). The female/male ratio was 2.1/1 (19 females and 9 males) in the study.

Symptoms: Suboccipital pain and numbness in extremities were the most common symptoms in the Duraplasty and Dural Splitting Groups (16/17, and 10/11, respectively). Various other symptoms such as gait disturbance, extremity pain, tremors, dysphagia, tinnitus were also present in the chart reviews; however, the groups differed from each other only regarding the gait disturbance (p=0.04), and the other comparisons between the groups revealed insignificant results (p>0.05).

Neurological Findings: Sensory deficit was the most common neurological finding in the Duraplasty and Dural Splitting groups (15/17, and 8/11, respectively). Other identified neurological signs were motor deficits, hyperactive reflexes, and cerebellar signs. The only significant difference between the two groups was in terms of cerebellar signs; 13 patients in the Duraplasty Group (n=17), and only two patients in the Dural Splitting Group (n=11) had manifested cerebellar signs (p=0.004).

Accompanying Pathologies: Syringomyelia was the most common preoperatively co-existing pathology in the Duraplasty and Dural Splitting Groups (9/17, and 5/11, respectively). Scoliosis, intracranial arachnoidal cyst, atlas occipitalization, basilar invagination, and Klippel-Feil syndrome were the other co-existing pathologies. No statistically significant difference was present between the two groups regarding associated pathologies (p>0.05).

Herniated Tonsil Length: There was no difference between the groups regarding the length of the herniated tonsil measured preoperatively (p>0.05). The herniated tonsil length was determined to have no significant relationships with the presence of accompanying syringomyelia (p=0.43), sensory deficit (p=0.48), motor deficit (p=0.49), hyperactive reflexes (p=0.45), and cerebellar signs (p=0.11).

Duration of the Operation: The difference between the Duraplasty and Dural Splitting Groups regarding the duration of operation (194±37 minutes and 103±18 minutes, respectively) was statistically incredibly significant (p=0.001).

Complications: The most common complication was cerebrospinal fluid (CSF) fistula in the Duraplasty Group (9/17 cases), whereas no CSF fistula was determined in the Dural Splitting group (0/11); the difference between the two groups was statistically significant (p=0.004). Superficial wound infection and meningitis were the other developing complications in the patients with no difference between the groups (p>0.05).

Duration of Hospitalization: The difference between the Duraplasty and Dural Splitting Groups regarding the duration of hospitalization (13.12±11.00 days and 7.45±8 days, respectively) was statistically significant (p=0.009).

Tonsillo-Dural Distance: We determined in our measurements on the postoperatively performed MRI studies that the difference between the Duraplasty (4.59±1.80 mm) and Dural Splitting (3.55±1.64 mm) Groups was significant regarding the tonsillo-dural distance (p=0.017).

The clinical features, radiological imaging results, and clinical and radiological outcomes of the patients were presented in Table 1.

Table 1. The clinical features, radiological imaging results, and clinical and radiological outcomes of the patients

	Duraplasty (n=17)	Dural splitting (n=11)	Total (n=28)	P value
Age (years) (Mean±SD)	42.41±15.41	39.82±8.96	41.39±13.12	
Symptoms				
Suboccipital pain	16	10	26	1.00
Numbness in extremities	16	10	26	1.00
Extremity pain	12	9	21	0.67
Gait disturbance	10	2	12	0.04
Tremor	1	0	1	1.00
Dysphagia	1	0	1	1.00
Tinnitus	1	1	2	1.00
Urinary incontinence	2	0	2	0.51
Neurological Findings				
Sensory deficit	15	8	23	0.35
Motor deficit	7	3	10	0.69
Hyperactive reflexes	10	6	16	1.00
Cerebellar signs	13	2	15	0.004
Tonsillar Herniation Length in Preop. MRI (mm) (Mean±SD)	11.53±4.45	11.82±2.89	11.64±3.85	0.711
Accompanying Pathologies				
Syringomyelia	9	5	14	1.00
Scoliosis	3	3	6	0.65
Klippel-Feil syndrome	0	1	1	0.39
Intracranial arachnoidal cyst	2	0	2	0.50
Atlas occipitalization	2	1	3	1.00
Basilar invagination	3	2	5	1.00
Duration of the Operation (minutes) (Mean±SD)	194±37	103±18		0.001
Complications				
CSF fistula	9	0	9	0.004
Superficial wound infection	7	3	10	0.69
Meningitis	2	0	2	0.51
Duration of Hospitalization (days) (Mean±SD)	13.12±11.00	7.45±8.00		0.009
Tonsillo-Dural Distance in Postop. MRI (mm) (Mean±SD)	4.59±1.80	3.55±1.64	4.18±1.79	0.017
Follow-up Period (months) (Mean±SD)	21.63±10.00	22.73±8.00		0.45

VAS Score: It was determined in both the Duraplasty and Dural Splitting groups that the VAS scores of the patients statistically significantly decreased with time postoperatively (p=0.001 and p=0.001, respectively). When the preoperative, postoperative 6-month and 12-month VAS scores were compared between the Duraplasty and Dural Splitting Groups, no significant differences were determined (p>0.05).

Neck Disability Index (NDI): It was determined in both the Duraplasty and Dural Splitting groups that the NDI scores of the patients statistically significantly decreased with time postoperatively (p=0.001 and p=0.003, respectively). When the preoperative and postoperative 6-month NDI scores were compared between the Duraplasty and Dural Splitting Groups, no significant differences were determined (p>0.05).

Neurological Scoring System (NSS): It was determined in both the Duraplasty and Dural Splitting groups that the NSS scores of the patients statistically significantly increased with time postoperatively (p=0.001 and p=0.003, respectively). When the increase of the NSS score from the preoperative period to the postoperative 6th month were compared between the Duraplasty and Dural Splitting Groups, no significant difference was determined (p>0.05).

Modified Japanese Orthopedic Association (JOA) Score: It was determined in both the Duraplasty and Dural Splitting groups that the modified JOA scores of the patients statistically significantly increased with time postoperatively (p=0.001 and p=0.006, respectively). When the improvement rate of the JOA score from the preoperative period to the postoperative 6th month was compared between the Duraplasty and Dural Splitting Groups, no significant difference was determined (p>0.05).

Chicago Chiari Outcome Scale (CCOS) Score: It was determined that no significant difference was present between the Duraplasty and Dural Splitting Groups regarding the postoperative 12-month CCOS score (p>0.05).

Syrinx Cavity/Medulla Ratio: In patients with syringomyelia, reduction of the syrinx cavity/medulla ratio from the preoperative period to the postoperative 6th-month was determined to be statistically significant in the Duraplasty and Dural Splitting Groups (p=0.001 and p=0.007, respectively). No significant differences were present between the Duraplasty and Dural Splitting Groups regarding the syrinx cavity/medulla ratio preoperatively and also 6 and 12 months postoperatively (p>0.05).

The distribution of the scores of Visual Analog Scale, Neck Disability Index, Neurological Scoring System, Modified Japanese Orthopedic Association, and Chicago Chiari Outcome Scale, and the Syrinx Cavity/Medulla Ratio in the Duraplasty and Dural Splitting Groups were presented in Table 2.

DISCUSSION

In this retrospective study, we aimed to determine the features, advantages, and disadvantages of the duraplasty and dural splitting methods following posterior fossa decompression in 28 patients with the Chiari Type-I malformation and determined no significant differences between them regarding the evaluations using the VAS, Chicago Chiari Outcome Scale, Neck Disability Index, Neurological Scoring System, and the modified JOA scores.

Table 2. The distribution of the scores of Visual Analog Scale, Neck Disability Index, Neurological Scoring System, Modified Japanese Orthopedic Association, and Chicago Chiari Outcome Scale, and the Syrinx Cavity/Medulla Ratio in the Duraplasty and Dural Splitting Groups

	Duraplasty (n=17)	Dural splitting (n=11)	Total (n=28)	P Value
Visual Analog Scale (mean±SD)				
Preoperative	8.00±1.54 (n=17)	8.73±1.19 (n=11)	8.29±1.44 (n=28)	0.264
Postop. 6th month	4.88±1.49 (n=17)	5.27±1.19 (n=11)	5.04±1.37 (n=28)	0.677
Postop. 12th month	2.40±1.88 (n=15)	1.60±1.43 (n=10)	2.08±1.73 (n=25)	0.285
P Value	0.001	0.001		
Neck Disability Index (mean±SD)				
Preoperative	32.53±9.02 (n=17)	37.27±5.44 (n=11)	34.39±8.05 (n=28)	0.175
Postop. 6th month	15.47±10.47 (n=17)	14.73±9.57 (n=11)	15.18±9.95 (n=28)	0.963
P value	0.001	0.003		
Neurological Scoring System (mean±SD)				0.458
Preoperative	22.12±4.50 (n=17)	23.18±3.18 (n=11)	22.54±4.00 (n=28)	
Postop. 6th month	26.29±3.33 (n=17)	27.45±1.97 (n=11)	26.75±2.89 (n=28)	
P Value	0.001	0.003		
Modified Japanese Orthopedic Association (JOA) Score (mean±SD)				0.208
Preoperative	14.24±3.91 (n=17)	15.00±3.10 (n=11)	14.54±3.57 (n=28)	
Postop. 6th month	15.94±3.07 (n=17)	16.64±1.63 (n=11)	16.21±2.59 (n=28)	
P Value	0.001	0.006		
Chicago Chiari Outcome Scale (mean±SD)				
Postop. 12th month	12.76±1.85 (n=17)	13.55±1.86 (n=11)	13.07±1.86 (n=28)	0.458
Syrinx Cavity/Medulla Ratio				
Preoperative	0.62±0.26	0.77±0.16	0.68±0.24	0.240
Postop. 6th month	0.47±0.22	0.61±0.12	0.51±0.20	0.371
Postop. 12th month	0.32±0.15	0.34±0.22	0.33±0.17	0.943
P Value	0.001	0.007		

On the other hand, significant differences were present, favoring the dural splitting technique regarding the operation time, hospital stay, and complication rates.

A consensus has not been reached yet on the surgical treatment of Chari Type-I malformations. Posterior fossa decompression, followed by duraplasty, has been the most frequently preferred surgical method. Posterior fossa decompression, followed by dural splitting, described as peeling the external dura layer, has recently been introduced to neurosurgical practice and has been used as an alternative surgical technique in our department since 2014 (8-10).

Chiari Type-I malformations have been reported to be symptomatic in young adults, aged within the range of 25-45 years, with a predominance of females. Bao et al. reported the mean age as 42.3 years and female/male ratio as 1.22/1, whereas the mean age was 25 years and female/male ratio was 3/1 in the study conducted by Milhorat et al. (11, 12). In our study also, Chiari Type-I malformation was determined to be more common in females and to manifest its symptoms in young adulthood, consistent with most of the published studies in the literature.

The most common symptom of patients with Chiari Type-I malformation presenting to physicians has been reported as pain, starting from the suboccipital region and spreading to the head and neck, because of brain stem, medulla, lower cranial nerves, cerebellum, and spinal cord compression in the studies of Chotai et al. (98%), and Gilmer et al. (93.1%) (9,13). Kotil et al. reported numbness in upper extremities with a frequency of 90% (10). Our study was consistent with results of these studies regarding the symptom distribution.

Syringomyelia was the most common accompanying pathology in our series. The literature review revealed frequencies of syringomyelia between 30-85% (9, 11, 14). Various bone anomalies such as scoliosis, basilar invagination, cervical vertebral fusion, incomplete ossification of C1 vertebra, and occipitalization of the atlas bone have also been reported to accompany Chiari Type-I malformations (15-17). The distribution of accompanying pathologies in our patients was like those reported in the literature.

Currently, the most commonly used criterion to diagnose a Chiari Type-I malformation is detecting cerebellar tonsillar herniation of 5 mm or more through the foramen magnum with MRI (5, 18). We had used that criterion to diagnose our patients as well. The absence of herniated tonsil length's significant relationships with sensory/motor deficits and cerebellar signs in our study suggest that even though the tonsillar herniation is the pathological cause, the main reasons for symptoms are the pressure gradient occurring within the craniocervical junction, and blockage of CSF circulation.

In our department, the VAS score, the modified JOA score, the neurological Scoring System, and the Chicago Chiari outcome Scale have been used for preoperative and postoperative assessments since 2014. Even though VAS score is not a test specific to Chiari malformations, it is easily applicable and can be used for pain assessment (19). In our study, we determined an incredibly significant (almost 75%) reduction of VAS score when the preoperative and 12-month postoperative VAS scores of the patients were compared, showing that the two methods were highly effective but not superior to each other regarding pain relief.

Godil et al. reported the neck disability index (NDI) to be one of the efficient tests regarding assessment of patients' pain and daily activities (20). Vakharia et al., investigating the effectiveness of foramen magnum decompression in patients with syrinx- and non-syrinx-related Chiari malformations, reported a reduction of NDI from 18 points (preoperatively) to 10 points on postoperative follow-up (21). In our study, both groups had similar NDI values at the same time-points but encountered incredibly significant reductions (over 50%) with time, and such reductions were consistent with Godil et al's and Vakharia et al's studies. On the other hand, the mean NDI values of both groups in our study were significantly higher than those reported in the literature. We have the opinion

that the prolonged duration from the initial diagnosis to the operation might have led patients to encounter pain for longer than one year.

The modified JOA score has been in clinical practice as an evaluation tool regarding clinical outcome in neurosurgery and orthopedics (19). Several studies investigating the JOA scores in Chiari malformations were published in the literature (22, 23). In a study published in 2007 by Ono et al., the relationships of foramen magnum decompression with scoliosis and syringomyelia in Chiari Type-I malformations were investigated; the preoperative and postoperative JOA scores of their patients with no scoliosis were reported as 14.4 and 15.8, respectively, and there was a statistically significant difference between them (24). Our results regarding the JOA score were similar to Ono et al's study; even though the two surgical methods were not superior to each other, both methods created significant differences between the preoperative and postoperative periods regarding the indices such as self-care, mobility, and urinary continence, assessed by the modified JOA scoring system.

Because Chicago Chiari Outcome Scale (CCOS) can evaluate pain-related factors and others such as occupation, school, and domestic affairs, it has been reported to be one of the most appropriate tests to evaluate the postoperative results of patients with Chiari Type-I malformations (19, 25). In our study, even though the mean CCOS score of the Dural Splitting group was slightly higher than the Duraplasty Group on the postoperative 12-month follow-up evaluation, the difference was statistically insignificant, revealing that the groups were not superior to each other regarding CCOS assessment. A similar result was very recently reported by Pandey et al. (26); when they compared their patients in whom either duraplasty or dural splitting was performed, they found that both procedures were equally effective in terms of CCOS score.

We determined in our study that the duraplasty and dural splitting methods were not superior to each other regarding the management of co-existing syringomyelia. Both methods led to a significant reduction of syrinx cavity /medulla ratio. Controversial reports have been published in the literature. Kotil et al. reported a similar result, a reduction of the ratio in 50% of their patients in whom a dural-splitting procedure was performed (10). A recent study by Oral et al. reported reduction of 49.6% and 54.6% regarding syrinx regression in dural splitting and duraplasty groups, respectively (27). On the other hand, Erdogan et al. determined an increased reduction ratio of syrinx cavity in their patients with a dural patch, and recommended that the first line of surgical treatment should be the dural splitting technique and if not successful, should be proceeded with duraplasti (28).

The dural splitting method lasting for nearly half the operative time compared to duraplasty in our study suggested that patients were exposed to lower anesthetic doses, and dural splitting was superior to duraplasty in this aspect. Limonadi et al. reported a study with a similar comparison result; the operative time was 169 minutes in their duraplasty series, whereas 99 minutes when they performed dural splitting (7). Kotil et al. reported a similar operative time (95 minutes on average) for dural splitting (10).

Complications that might develop should be taken into consideration while aiming to accomplish adequate decompression in surgical management of Chiari Type-I malformations. Complication rates up to 42% have been reported for duraplasty, whereas 10%, a rate of nearly one-fourth of duraplasty's complication rate, has been reported for dural splitting method (9). Similarly, Romero et al., and Erdogan et al. reported lower complication rates of dural splitting than duraplasty, regarding particularly the development of a CSF fistula (28, 29). Chauvet et al., in their report of 11 patients in whom dural splitting was performed, reported no complications such as CSF fistula, meningocele, or meningitis (30). We had a similar result in our study; all the nine patients who had developed a CSF fistula were in the Duraplasty Group. We think that the dural splitting technique is more advantageous and superior when compared to duraplasty regarding the complication development rate.

Complications, when they develop, prolong the hospitalization period, even when they are successfully managed. The dural splitting method required remarkably less hospitalization time than the duraplasty method in our study. Our study results were consistent with the published studies in the literature. Limonadi et al. and Erdogan et al. reported similar results in their studies, longer hospitalization times in duraplasty (14.2 days vs. 5.4 days in Erdogan et al.'s study), when compared to dural splitting (7, 28). According to our results, and supported by the published studies in the literature, the dural splitting is a surgical method with a lower complication rate, shorter hospitalization period, lower treatment cost, and similar efficacy when compared to the duraplasty method.

To our knowledge, no study assessing the patients' status with Chiari Type-I malformations through such a wide range of scoring methods has been published in the literature. This was one of our study's advantages. Another advantage of the study was being conducted in a single center because the investigated neurosurgical methods were standardized within that center.

The retrospective nature and the relatively small number of the patients in both groups were the study's limitations.

CONCLUSION

Even though duraplasty following posterior fossa decompression is an effective and commonly preferred method for surgical treatment of Chiari Type-I malformations, the frequent occurrence of complications, prolonged operation times, and prolonged hospitalizations, and accordingly increased costs draw this technique away from being the first line in surgical treatment.

Dural splitting method and microincisions on the inner dura layer provide outcomes as successful as the duraplasty method. Besides, the development rate of complications, particularly a CSF fistula, the durations of the operation and hospitalization are less in dural splitting than duraplasty. For these reasons, the dural splitting method should be considered a suitable alternative to duraplasty for treatment of patients with Chiari Type-I malformations. To increase the reliability of such a conclusion, a prospective study with a larger sample size should be conducted.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Ethics Committee for Clinical Research in Zonguldak Bülent Ecevit University (Date: 19.12.2019, Deision No: 2018-244-19/12).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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