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Decompressive Craniotomy for Malignant Middle Cerebral Artery Infarction: A Prospective Cohort Study

Malign Orta Serebral Arter Enfarktüsü İçin Dekompresif Kraniyotomi: Prospektif Bir Kohort Çalışması

***Hasan Kamil SUCU*[1] *Mustafa Kemal ARI*[2] *Selin BOZDAG*[3]**

ÖZ

Amaç: Malign orta serebral arter (Middle Cerebral Artery- MCA) infarktları için ölüm oranı çok yüksektir. Dekompresif kraniyotomi (DK) mortaliteyi azaltıyor gibi görünse de yaşam kalitesi halen güncel bir tartışma konusudur. Yüksek hacimli üçüncü basamak hastanemizde medikal veya cerrahi olarak tedavi edilen malign MCA enfarktüslü hastaların sonuçlarını sunmayı amaçladık.
Araçlar ve Yöntem: Çalışma prospektif kohort olarak tasarlanmıştır. Kriterleri karşılayan her hastaya DK önerildi, kabul etmeyenler kontrol medikal tedavi grubu olarak takibe alındı. Hastalar ameliyat öncesi, ameliyat sonrası erken dönem ve 1./3./6./12. aylarda değerlendirilmiştir.
Bulgular: Kırk iki hasta çalışmaya dahil edildi (17/ameliyat, 25/medikal). Her takip döneminde DK hastalarının hayatta kalma oranları, sadece tıbbi tedavi alanlardan daha yüksekti. Bu fark postoperatif 1., 3. ve 6. aylarda da anlamlıydı. Ek olarak, modifiye Rankin Ölçeği incelemesi, DK'nin her kontrol periyodunda üstün olduğunu göstermiştir.
Sonuç: Çalışmamızda DK uygulanan hastaların mortalitesinin (sadece medical tedavi uygulananlara göre daha düşük olsa da) diğer serilere göre daha yüksek olması, ameliyat sırasındaki nörolojik durumun kötü olması ile açıklanabilir. Ameliyat endikasyonu için hastanın durumunun çok kötüleşmesi beklenmemelidir. Bu amaçla hastaların nörolojik durumundaki kötüleşmenin erken dönemde sık muayene ile beyin cerrahına bildirilmesi gerekmektedir. Nörolojik durumunda kötüleşme olasılığı olan hastaların beyin cerrahisi kliniğine sevk edilmesi alternatif bir çözüm olabilir.

Anahtar Kelimeler: dekompresif kraniyotomi; inme; malign orta serebral arter enfarktüsü

ABSTRACT

Purpose: For malignant middle cerebral artery (MCA) infarctions, the mortality rate is very high. Although decompressive craniotomy (DC) appears to reduce mortality, the quality of life remains a current topic of debate. We aimed to present the outcomes of patients with malignant MCA infarctions treated medically or surgically at our high-volume tertiary care hospital.
Materials and Methods: The study was designed as a prospective cohort. Decompressive craniotomy (DC) was offered to all patients meeting the criteria, while those who declined were included in the control group receiving medical treatment. Patients were evaluated preoperatively and early postoperatively and also in the follow-ups at 1, 3, 6, and 12 months.
Result: Forty-two patients were included in the study (17/surgery, 25/medical). Survival rates of those who received DC in each follow-up period were higher than those who received only medical treatment. This difference was also significant at the postoperative 1st, 3rd, and 6th months. In addition, the modified Rankin-Scale examination showed that DC was superior in each control period.
Conclusion: In our study, the higher mortality among patients who underwent DC, albeit lower than those treated with medical therapy alone, could be attributed to poorer neurological status at the time of surgery compared to other series. The indication for surgery should not wait until the patient's condition deteriorates significantly. Therefore, it is crucial to promptly report any neurological deterioration observed during early period to the neurosurgeon. Referring patients who are at risk of neurological decline to a neurosurgery clinic could serve as an alternative solution.

Keywords: decompressive craniotomy; stroke; malign middle cerebral artery infarction

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[1]Department of Neurosurgery, Izmir Katip Celebi University Faculty of Medicine, Ataturk Training and Research Hospital, Izmir, Turkey.
[2]Department of Neurosurgery, Izmir Ataturk Training and Research Hospital, Izmir, Turkey.
[3]Department of Neurosurgery, Izmir Katip Celebi University Ataturk Training and Research Hospital, Izmir, Turkey.
Corresponding Author: Selin Bozdağ, Department of Neurosurgery, Izmir Katip Celebi University Ataturk Training and Research Hospital, Izmir, Turkey.
e-mail: selin.bzdg@gmail.com

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INTRODUCTION

Despite the relative decrease in stroke frequency due to the developments in preventive medicine in the 1960s and 1970s, it is still the second leading cause of both disability and death on a global scale.[1] The prevalence of strokes worldwide was 1.322 per 100.000 individuals, and the incidence was 156 per 100.000 individuals in 2016, with slightly higher numbers in the US at 2.320 prevalence and 184 incidences per 100.000 individuals in the same year.[1,2] Although age-standardized rates notably dropped, the annual count of stroke cases and related fatalities increased between 1990 and 2019, particularly among those over 70 years old. This burden is particularly pronounced in the World Bank's low-income group.[3] The mounting impact of strokes is on the rise, posing a substantial obstacle for healthcare systems worldwide.

Nearly 35 years ago, Hacke et al. introduced the term "malignant" to describe acute and complete middle cerebral artery (MCA) territory infarction accompanied by cerebral edema, causing rapid neurological deterioration and herniation. The prognosis is poor in hemispheric infarcts accompanied by massive edema. For malignant MCA infarcts, the mortality rate is very high (%80), and severe sequelae remain in the survivors. Managing intracranial pressure remains a crucial challenge in cases of severe post-stroke cerebral edema. The medical approaches include head elevation, hyperventilation, osmotic therapy, and sedation. While osmotic therapy's efficacy is debated, it can be a temporary solution until surgical intervention is feasible.

Kjellberg and Prieto reported a case series of 73 patients treated with bifrontal decompressive craniectomy for massive cerebral edema in 1971. One of them was a patient with a massive stroke who did not survive.[4] The first three patients who underwent hemicraniectomy for acute massive cerebral infarction were published by Rengachary et al. in 1981. All three patients survived, although severe neurological deficits persisted in two.[5] Until the first European randomized trials emerged, most publications demonstrating the advantageous outcomes of surgical decompression consisted mainly of retrospective case series or nonrandomized prospective studies.[6-8] Three initial European trials, the French DECIMAL (DEcompressive Craniectomy In MALignant middle cerebral-artery infarcts), the German DESTINY (DEcompressive Surgery for the Treatment of malignant INfarction of the middle cerebral artery), and the Dutch HAMLET (Hemicraniectomy After Middle cerebral artery infarction with Life-threatening Edema Trial) were the first to prove that decompressive craniectomy (DC) was associated with decreased mortality.[9-11]

However, the patient selection criteria in the pioneering studies found in the literature imposed certain restrictions. Therefore, our study aimed to investigate the demographic characteristics, timing considerations, and outcomes of decompressive craniectomy (DC) performed for malignant middle cerebral artery (MCA) infarctions at our highly active tertiary hospital. We adopted an unrestricted approach to patient selection, without constraints such as age or symptom onset time.

MATERIALS and METHODS

In this study, patients with MCA infarction who were hospitalized and treated medically and surgically in our neurology and neurosurgery clinics were evaluated prospectively. This study was approved by Izmir Ataturk Training and Research Hospital Local Ethics Committee (dated 7/11/2003 and number 2003/7). The study was planned as a prospective cohort. Therefore, decompressive surgical treatment was recommended for every patient who met the criteria. Those who did not accept were followed as the control medical treatment group, and the recruitment period lasted two years.

Inclusion Criteria

1- Presence of arteria cerebri media infarction. (The infarct was required to occur in at least half of the area supplied by the middle cerebral artery. Not only cases of pure middle cerebral artery infarctions but also those of anterior cerebral artery infarction added to middle cerebral artery infarctions were also included in the study.)

2- Presence of at least 5 mm pineal gland shift or at least 10 mm septum pellucidum shift in brain computed tomography (CT) imaging.

3- The sum of Glasgow Coma Scale Eye (E) and Motor (M) scores ≤7 (Presence of intubation or aphasia in patients with stroke poses a problem in the use of the unmodified form "Eye-Motor-Verbal" Glasgow Coma Scale (GCS). Therefore, we chose to eliminate the verbal subscale to deal with the untestable verbal subscale.)

Among patients hospitalized in the Neurology and Neurosurgery clinics for MCA infarction, surgery was recommended for those who met the specified criteria upon admission or experienced a deterioration in their neurological status during follow-up, subsequently meeting these criteria.

Exclusion Criteria

1- Hemorrhagic complications requiring internal decompression.

Surgery

A fronto-parieto-occipital craniotomy of at least 10*10 cm, including the temporal base was performed through an inverted question mark incision. The maximal extension of the craniectomy into the middle cranial fossa and the optimal proximity of the craniectomy edge to the midline were targeted. The dura is suspended on the calvarial bone edges. Meanwhile, another surgeon took a large fascia lata graft. Then, the dura was opened as an envelope, and duraplasty was performed with the graft taken to allow the brain to expand (Figure 1). Next, the skin layers were closed by placing a subgaleal suction drain. Finally, the bone flap was placed on the thigh from which the graft was taken.

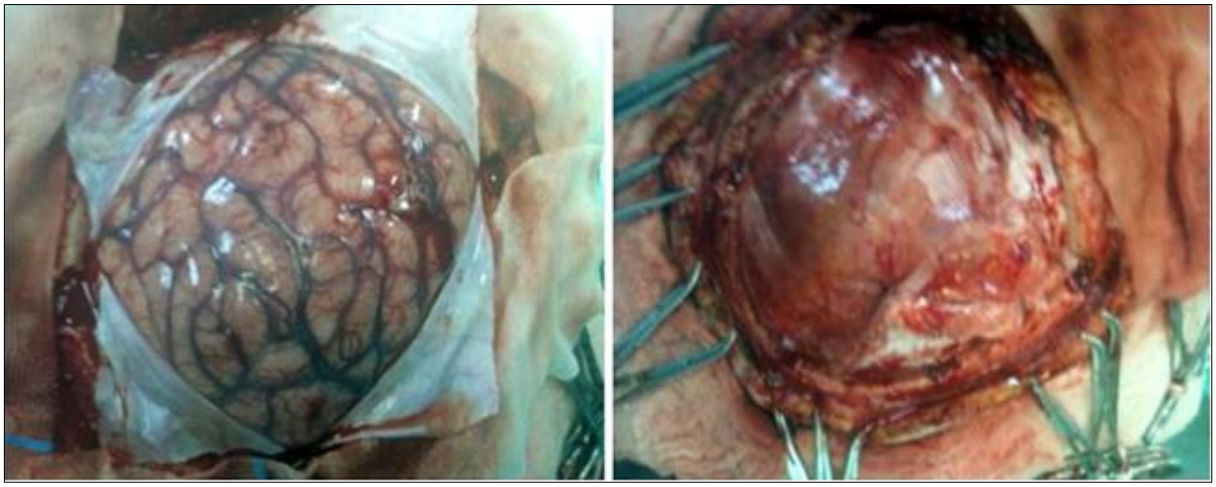

Figure 1. Surgery a. After opening the dura b. Duraplasty.

Medical Therapy

It was tried to give the same medical treatment to each patient as much as possible, whether surgical treatment was applied or not. Except for case-specific differences, the medical treatment template was as follows:

- Admission to the intensive care unit
- Reasonable control of diabetes, if present
- Antiplatelet therapy
- Anticoagulant therapy in patients with atrial fibrillation
- Blood pressure management
- IV fluids
- Prevention hyperthermia
- Head elevation
- Osmotic therapy (Mannitol 20% 0.5-2 g/kg/day): for clinical deterioration from cerebral edema
- Mechanical ventilator support as appropriate

Radiological Follow-Up

We procured CT scans for all patients during the immediate postoperative phase (within 24 hours). In addition, the surviving patients' computed tomographies were obtained postoperatively in the 1st, 3rd, 6th, and 12th months (Figure 2).

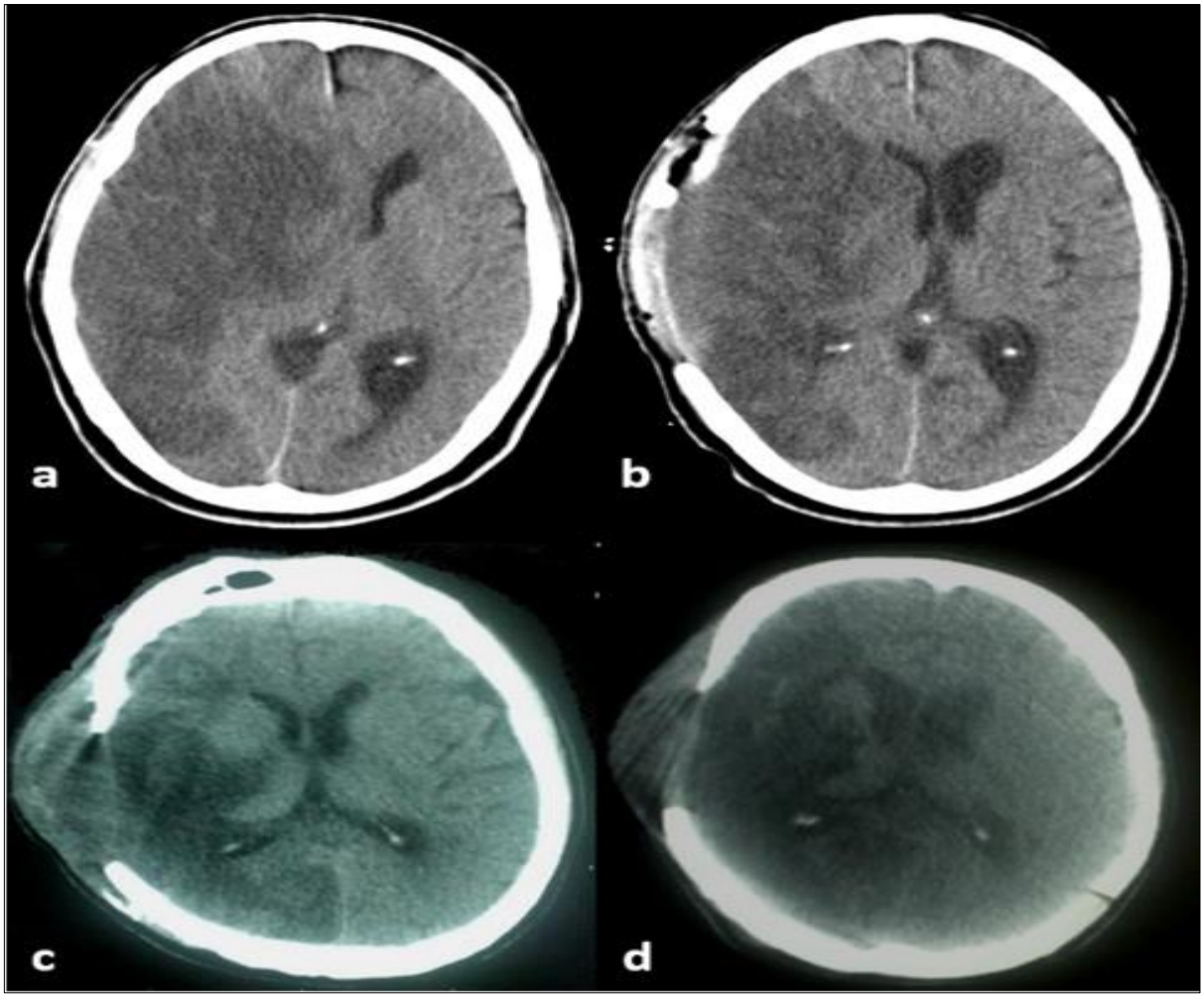

Figure 2. Radiological follow-up a. Pre-operative, b. Postoperative first 24th hour, c. Postoperative 1st month, d. Postoperative 1st year.

Clinical Follow-Up

Patients were evaluated with the Scandinavian Stroke Scale and Glasgow Coma Scale in the pre-operative period and with the Modified Rankin Scale, Barthel Index, and Glasgow Outcome Scale at the 1st, 3rd, 6th, and 12th months postoperatively.[12-15]

Statistical Analysis

The variables underwent analysis using the Mann-Whitney U test and Pearson's chi-square test (or Fisher's exact test when applicable). Results were considered significant if the p-value was less than 0.05.

RESULTS

A total of 42 patients were included in the study. Seventeen of these patients received a combination of surgery and medical treatment, while the remaining 25 patients received medical treatment alone. First, 3rd, 6th, and 12th-month follow-ups could be performed in all patients except the 42nd. Patient 42 was alive at the 3rd-month follow-up. Then, the patient became lost to follow up.

Survival rates of those who received surgical treatment in each follow-up period were higher than those who received only medical treatment. This difference was also statistically significant at the postoperative 1st, 3rd, and 6th months (Table 1). The Modified Rankin Scale examination

showed that surgical treatment was superior in each control period (Table 2).

The mean age of the patients was 64.3 (Min 38; Max 86; SD:13.13). Half of the patients were over 65 (21 patients, 50%). No significant difference was found in mortality rates in any control periods when the 65 and younger age group was compared with the over-65 age group. In addition, no significant difference was found in the mean age of the patients who survived and those who died in any follow-up period.

Male patients (21 patients) and female patients (21 patients) were at the same rate. No relationship was found between gender and mortality rate in any follow-up period.

There was no difference between the surgical and medical treatment groups regarding Glasgow Coma Scale (EMV) scores at the beginning of treatment. The total E + M scores were a minimum of 2 and a maximum of 7 (median 4.50). In each follow-up, the E+M scores at the time of application were higher in the living than in the deceased. This difference was statistically significant in the postoperative 1st, 3rd, and 6th months (Mann-Whitney U test, p=0.003; 0.021 and 0.032, respectively). While the sum of E and M was 2-4 in 21 patients at the study enrollment time, it was 5-7 in 21 patients. After one month, all 21 patients with an E+M score between 2 and 4 died, regardless of whether they underwent surgery. The survival disadvantages of this group were statistically significant in the 1st, 3rd, and 6th months postoperatively (Table 3).

Table 1. Relationship between treatment modality and mortality at 1st, 3rd, 6th, and 12th months.

Period	**1st-month n (%)**		**3rd-months n (%)**		**6th-months n (%)**		**12th-months n (%)**	
Treatment	Dead	Alive	Dead	Alive	Dead	Alive	Dead	Alive
Medical	24 (96.0%)	1 (4.0%)	25 (100.0%)	0 (0.0%)	25 (100.0%)	0 (0.0%)	25 (100.0%)	0 (0.0%)
Surgery	11 (64.7%)	6 (35.3%)	12 (70.6%)	5 (29.4%)	12 (75.0%)	4 (25.0%)	13 (81.3%)	3 (18.8%)
p-value*	0.012		0.007		0.018		0.053	

*Fisher's Exact Test

Table 2. The relationship between the treatment method and the Modified Rankin Scale (mRS) rates at the end of the 1st, 3rd, 6th, and 12th months.

Period	**1st-month**	**3rd-month**	**6th-month**	**12th-month**
Treatment	**mRS (number)**	**mRS (number)**	**mRS (number)**	**mRS (number)**
Medical	5 (1), 6 (24)	6 (25)	6 (25)	6 (25)
Surgery	4 (2), 5 (4), 6 (11)	4 (4), 5 (1), 6 (12)	4 (3), 5 (1), 6 (12)	4 (3), 6 (13)
p-value*	0.008	0.004	0.009	0.026

*Mann-Whitney U test.

Table 3: Relationship between admission E and M score totals and mortality rates at the end of 1st, 3rd, 6th, and 12th months.

GCS	**Period**	**1st-month**		**3rd-month**		**6th-month**		**12th-month**	
(E+M)	**Treatment**	**Dead**	**Alive**	**Dead**	**Alive**	**Dead**	**Alive**	**Dead**	**Alive**
E+M: 2–4	No surgery	15 (100.0%)	0 (0.0%)	15 (100.0%)	0 (0.0%)	15 (100.0%)	0 (0.0%)	15 (100.0%)	0 (0.0%)
	Surgery	6 (100.0%)	0 (0.0%)	6 (100.0%)	0 (0.0%)	6 (100.0%)	0 (0.0%)	6 (100.0%)	0 (0.0%)
	Total	21 (100.0%)	0 (0.0%)	21 (100.0%)	0 (0.0%)	21 (100.0%)	0 (0.0%)	21 (100.0%)	0 (0.0%)
E+M: 5–7	No surgery	6 (60%)	4 (40%)	10 (100.0%)	0 (0.0%)	10 (100.0%)	0 (0.0%)	10 (100.0%)	0 (0.0%)
	Surgery	5 (45.5%)	6 (54.5%)	6 (54.5%)	5 (45.5%)	6 (60%)	4 (40%)	7 (%70)	3 (%30)
	Total	11 (66.7%)	10 (33.3%)	16 (76.2%)	5 (23.8%)	16* (80.0%)	4* (20.0%)	17* (85.0%)	3* (15.0%)
p-value**		0.009		0.048		0.048		0.0107	

* Patient 42 was alive at the 3rd-month follow-up. Then it became lost to follow up.
**Fisher's Exact Test.

The mean time between the onset of symptoms and study enrollment was 2.8±1.7 days (0–7 days). Twenty-one patients were enrolled in the study within the first two days after the onset of the first symptoms, while the other 21 patients were included in the study 3 days or later. There was no difference in survival between these two groups at any time.

While the infarct area was only in the MCA supply area in 30 patients, there was at least one more infarct in the large artery supply area in 12 patients. No difference in mortality rates between the pure MCA infarcts and MCA+ACA infarcts existed in any control period. The mean pineal gland shifts of the patients at the time of study enrollment were 6.81±4.01 mm (0-12 mm), and the mean pre-operative septum pellucidum shifts were 14.33±3.19 mm (10-22 mm). There was no difference in the pre-operative

pineal gland or septum pellucidum shifts between patients who survived and those who died during any follow-up period.

Postoperative CT scan evaluations showed that the craniotomy areas met the targeted dimensions for maximum extension to the middle cranial fossa and optimal proximity of the craniectomy edge to the midline.

DISCUSSION

The data evaluation committee of three initial European randomized trials (the French DECIMAL, the German DESTINY, and the Dutch HAMLET) concluded the studies earlier than previously agreed and terminated them midway.[9-11] This premature termination can be explained by the fact that conducting a randomized study on this subject is challenging, as it causes legal and ethical hesitations. The study was initially designed to be randomized. However, the difficulty of not recommending surgery, although likely to benefit families, led to the study being planned as a prospective cohort.

The most striking difference between these studies' results and ours is that the total death rates are much lower than ours. After 12 months: in DESTINY 11/32 (%34), in DESTINY HAMLET 26/64 (%41), in DESTINY DECIMAL 19/38(%50), in this study, 36/39(92%).[9-11] This significant difference is most likely due to patient selection. In all three published studies, there is a significant difference with this study regarding patient selection, especially in the pre-operative level of consciousness, age, and the time between symptom onset and randomization. Kilincer et al. showed that the pre-operative Glasgow Coma Scale score of 8 or above is the most important predictor of good outcomes.[16]

In the DECIMAL[9] and DESTINY[10] studies, patients had a much better pre-operative neurologic status than those in this study. Close to our research, the HAMLET study included more severe strokes than the DECIMAL or DESTINY studies. The DECIMAL and DESTINY studies did not give[9-11] Glasgow coma scale scores. Still, it is understood from the inclusion criteria that only patients with a tendency to sleep, with an E (eye) response of 3, could be included in the study.[9,10] A patient with a right hemisphere lesion without aphasia and EMV values of 3-6-5, 14 points, can be randomly selected in the DECIMAL and DESTINY studies.[9,10] On the other hand, a patient with a right lesion in the HAMLET study should have a total EMV of 13 or less.[11] The HAMLET study's requirement for a patient with a left hemisphere lesion (aphasia) to have an E+M sum of 9 or less is theoretically compatible with the DECIMAL and DESTINY studies.[9-11] This study included more severe stroke patients from all three studies. (E+M total should be seven or less for both right and left lesions).

In their retrospective cohort study published in 2008, Fiorot et al. reported that neither mortality nor functional outcomes improved with surgery. These findings were ascribed to the unfavorable neurological state of the patients when the surgical decision was made.[17] Although the overall survival rate was meager, our findings indicated surgical decompression decreased mortality among the control group after the 1st, 3rd, and 6th months.

Another critical difference with this study is that the DESTINY and DECIMAL studies also found that acceptable outcomes (Modified Rankin Scale scores between 1-3) increased with surgery.[9,10] However, such a conclusion could not be reached in the HAMLET study.[11] In this study, none of the three patients who lived at the end of 12 months could decrease to 3 points. However, all three patients who survived at the end of 1 year had a modified Rankin Scale score of 4, indicating that the patients were not bedridden.

In the HAMLET study, the acceptable mRS score (mRS 1-3) was the same (25%) in both treatment groups one year later. However, post-surgical death rates decreased significantly (59% in the medical treatment group vs. 22% in the surgical decompression group, p=0.002). Still, the survivors were not in the acceptable group (mRS 1-3) but have accumulated in the poor outcome group (mRS 4 -5). In other words, while surgical decompression decreased mortality, it did not increase the acceptable outcome but only increased the group of patients with severe deficits and bedridden. Furthermore, in surviving patients, the surgical group was not better in terms of temperament, quality of life, and satisfaction of the patients and their relatives at the end of 1 year. In contrast, the physical

condition was better in the medical treatment group. In the same study, patients were divided into two groups according to aphasia, age (≤50 and 51-60), and the period between the onset of stroke and randomization (<48 hours and >48 hours). Except for the period of randomization, surgery has not been shown to reduce poor outcomes in any group (considering age and presence of aphasia). Only in the group randomized within the first 48 hours was the benefit of surgery shown if the poor result was taken as mRS 5-6 but not 4-6.

In the evaluation of 13 uncontrolled studies involving 138 patients, being older than 50 years emerged as the primary prognostic factor for unfavorable functional outcomes after surgical decompression.[18] One of the reasons for the higher death rate compared to the three randomized studies published in this study may be the inclusion of the older patient group in the study. Patients with a maximum age of 60 years (55 or less in DECIMAL) were included in all three studies.[9] If we had behaved similarly, we would not have included a significant portion of stroke patients in the study. Seventeen of our 39 patients (44%) were under 60, and only 12 (31%) were 55 or younger. In our opinion, it is inconvenient to make such a restriction beyond the need for it. The population encountered in daily practice and for which the answer to whether surgical decompression is beneficial is generally over 60 years old. In addition, after the study is done, if desired, it can be divided into subgroups according to age, and additional evaluations can be made quickly.

A significant difference between the DECIMAL and DESTINY studies from the HAMLET study and this study is the time from the onset of symptoms to enrollment.[9-11] This is a maximum of 30 hours in DECIMAL, 36 hours in DESTINY, and 96 hours in HAMLET.[9-11] In this study, however, there was no upper limit. The most prolonged period was seven days between the development of symptoms and surgery in the patients included in the study. This factor likely contributed to the fact that HAMLET's results were worse than DECIMAL and DESTINY, and our results were even worse than HAMLET's.[9-11]

In our opinion, the results of these three studies should be evaluated very carefully. Since the study cannot be performed blindly, it can be mentioned that there is no involuntary influence in the treatment. For example, 84% of surgical decompression cases in the HAMLET study were mechanically ventilated, compared to 16% in the medical treatment group.[11] Therefore, mechanical ventilation may have affected the result –positively. In addition, due to the nature of the surgery, it is difficult to evaluate the outcome blindly. In this study, as in DESTINY, outcome evaluation was not performed blindly.[10] In DECIMAL, blind evaluation was provided by covering the heads of the patients with a surgical cap.[9] Within the HAMLET trial, leveraging an account from a study nurse who interacted with the patient and their family, three neurologists, uninformed about the administered treatment, conducted the mRS assessment, thereby facilitating a partially blinded evaluation.[11] An unblinded assessment may result in a biased evaluator (for example, in favor of surgery) - involuntarily - underestimating the results of the other treatment (e.g., medical treatment) and vice versa.

Since it was written in some articles published after our study that a bone opening of 12 cm was required,[19-23] our minimum craniotomy opening of 10*10 cm could be a potential point of criticism. However, after the craniotomy was completed, a craniectomy was added to the temporal bone and part of the sphenoid wing, up to the temporal base, in each case. This procedure formed a bone gap with edges larger than 10 cm in almost every case.

Conclusion

The fact that the mortality rate of the patients who underwent surgery in this study (although lower than those who received only medical treatment) was higher than in the other series can be explained by the poor neurological condition at the time of surgery. Two primary practices can be implemented to reduce mortality rates further. First, it should not wait until the patient's condition deteriorates too much to make an indication for surgery. The predetermined threshold E+M value for the surgery can be determined as 8 or 9 instead of 7. Second, as soon as the patient's neurological condition reaches the limit of surgical indication, it can be operated on without worsening it. For this purpose, it is necessary to inform the neurosurgeon of the decrease in the neurological condition of the patients with frequent examinations in the early

period and to plan the surgery urgently. A specialist in the neurology clinic where patients with major infarcts are hospitalized should be particularly interested in this issue. Referring patients with the possibility of worsening to the neurosurgery clinic and following up may be an alternative solution. We believe setting any age limit for surgical indication may exclude a patient group likely to benefit from treatment and is unnecessary.

Conflict of Interest

The authors declare that there is not any conflict of interest regarding the publication of this manuscript.

Ethics Committee Permission

This study was approved by Izmir Ataturk Training and Research Hospital Local Ethics Committee (dated 7/11/2003 and number 2003/7).

Authors' Contributions

Concept/Design: HKS, MKA. Data Collection and/or Processing: HKS, MKA. Data analysis and interpretation: HKS, MKA, SB. Literature Search: HKS, MKA, SB. Drafting manuscript: SB. Critical revision of manuscript: HKS, MKA, SB. Supervisor: HKS.

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