Achalasia Treatment. Robotic Approach or Laparoscopy?

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Rezumat

Tratamentul acalaziei. Chirurgie robotică sau laparoscopie?

Introducere: În prezent persistă întrebarea dacă tratamentul de primă intenție în acalazie este endoscopic sau chirurgical. Diferența dintre rezultatele pe termen lung ale acestor aborduri este de asemenea important, cât și fezabilitatea lor.


Rezultate: Rata de recidivă este semnificativ mai mare în grupul DB (χ² = 16.81, DF = 1, p < 0.0001). Nu este o diferență semnificativă între grupei în ceea ce privește ameliorarea simptomatologiei. Rata de succes este comparabilă între robot și laparoscopie. Diferența semnificativă s-a confirmat și în ceea ce privește durata spitalizării, cu o medie de 4.78±1.59 zile în grupul robotic și 5.52±2.1 în cel laparoscopic (t = 2.40, DF = 124.34, p = 0.0177). Rata de esofagita postprocedurală este semnificativ mai mare în cazurile fara fundoplicatură și în grupul DB.

Concluzii: Acest studiu demonstrează ca abordul chirurgical este superior celui endoscopic privind rata de recidivă chiar daca rezultatele pe termen lung sunt comparabile. Rata de succes a fost asemănatoare între grupul laparoscopic și cel robotic.

Cuvinte cheie: acalazie, dilatare pneumatică, miotomie Heller, chirurgie minim invazivă, laparoscopie, robotică
Abstract

Background: Nowadays the question persists whether to choose the endoscopic or surgical method as the first treatment of choice for achalasia. Another debate topic is about the differences between the outcomes of the two approaches of minimally invasive surgical treatment and their feasibility.

Material and Methods: This retrospective observational study included 193 patients with achalasia treated between 2008 and 2021. The patients were divided into 2 groups (A and B): 152 with minimally invasive heller myotomy (HM), and 41 with pneumatic dilation (PD). Patients surgically treated were then subdivided into robotic group (RG) and laparoscopic group (LG).

Results: The recurrence rate was significantly higher in PD group ($\chi^2 = 16.81$, DF = 1, $p < 0.0001$), with a success rate of 63.4%, comparing with 92.7% in HM group. No significant difference was obtained between the 2 groups concerning symptom relief on patients successfully treated. The success rate was comparable between the robotic and laparoscopic groups ($p = 1$). Significant difference was obtained in length of hospital stay between the 2 groups, with a mean of 4.78±1.59 days in the RG and, respectively, 5.52±2.1 days in the LG ($t = 2.40$, DF = 124.34, $p = 0.0177$). Postprocedural esophagitis rates were higher in patients with no fundoplication (6 out of 37 · 16.2%) and in patients treated with pneumatic dilation (4 out of 26 · 15.4%) than in patients with fundoplication (4 out of 46 · 8.5%).

Conclusion: The present study indicates that surgery may be a better choice in fit patients for the treatment of achalasia. The procedure has a better success rate, even if the long-term outcomes are comparable in patients successfully treated. The success rate and long-term results were comparable between laparoscopy and robotic surgery.

Key words: achalasia, pneumatic dilation, Heller myotomy, minimally invasive surgery, laparoscopic, robotic

Introduction

Nowadays it is still a matter of debate to establish exactly which of the treatments proposed so far is the most effective for achalasia. The reasons are that achalasia is a rare condition and that all treatment methods require subjective tools for outcome evaluation. These are obvious limitations in evaluating the treatment’s success rate of any kind. Many studies report divergence between patient’s subjective symptomatic improvement and the objective results (1,2).

Current treatment methods for achalasia are palliative and include surgical, endoscopic or pharmacological methods. Their aim is to relieve symptoms by overcoming the outflow resistance due to the hypertonic sphincter. The treatment is considered successful when the postprocedural Eckardt score counts up to 3 or less (3).

The condition was often misdiagnosed and wrongly treated as gastroesophageal reflux disease (GERD). Nowadays, the high-resolution manometry (HRM) achieved an improvement, being the gold standard for the paraclinical diagnosis (4,5).

The incidence is similar in both sexes and typically occurs in adults, which peaks around 30 and 60 years (6).

For the time being the question persists whether to choose the endoscopic or surgical method as the first treatment of choice. Another debate topic would be about the differences between the outcomes of the two approaches of minimally invasive surgical treatment and their feasibility. Therefore, the aim of this study is to compare the short- and long-term outcomes of pneumatic dilation (PD) and minimally invasive Heller myotomy (HM) in patients with achalasia treated in our center.
Material and Methods

This retrospective observational study was conducted in Fundeni Clinical Institute of Bucharest, Romania. It included 193 patients with achalasia between 2008 and 2021. The inclusion criteria were: patients with primary achalasia based on endoscopic, radiographic and manometric findings and without specific previous treatment. The therapeutic methods available in our hospital were presented to the patients with all the related risks, benefits and costs. The patients were divided into 2 groups: with minimally invasive HM (group A - 152 patients), and with PD (group B - 41 patients). Patients surgically treated were then subdivided into robotic group (RG) A1 and laparoscopic group (LG) A2 (Fig. 1).

The following data were evaluated: age, gender, symptoms, preprocedural and post-procedural Eckardt score (for evaluation of symptom relief), length of hospital stay, success rate (need for another procedure in case of recurrent symptoms), presence of fundoplication, operative time, esophageal perforation or other accidents, conversion rate, postprocedural morbidity rate using Clavien-Dindo classification, gastroesophageal reflux during follow-up with/without presence of esophagitis. Follow-up data for an average of 24 months was obtained from all 41 patients of PD group and from 83 patients of HM group (Fig. 1). Data was obtained by either admission, same day admission or phone-call assessment.

The main purpose of this study was to evaluate the success rate of the two procedures, based on symptom relief and the need for another treatment of any kind. Another goal was to compare the differences between the approaches in groups A1-A2 using the above-mentioned criteria.

Figure 1.
HM – Heller Myotomy
PD – Pneumatic Dilations
RG – Robotic Group
LG – Laparoscopic Group
The study was approved by Ethics Board for using the patients’ data, and informed consent was obtained from all patients enrolled.

Data was collected in Microsoft Excel and the statistical analysis was performed with R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. Categorical variables were described in percentages and frequencies while continuous variables were described as median and range or mean ± standard deviation, after checking for normality. Chi-square test and Fisher’s exact test were used when comparing categorical variables. Continuous variables with quasi-normal distributions were compared using Welch’s T-test while if severe deviation from normality, appropriate non-parametric tests were applied. Differences were considered significant at a p-value of <0.05.

Results

Out of the total of 193 patients treated for achalasia, there were 152 surgical interventions (group A · HM) and 41 pneumatic dilations (group B · PD), as seen in (Table 1). Follow-up data was obtained from all 41 patients of PD group and from 83 patients of HM group. The maximum follow-up period in both groups was 60 months and the minimum was 12 months, with an average of 24 months.

The mean age in HM group was 49 years old, while in the PD group was 56.6 years old (t = 3.01, DF = 69, p = 0.0036).

The mean hospital stay was significantly higher in the HM group (5.11±1.9 days) than in the PD group (1.95±1.8 days), t = 9.67, DF = 63.61, p < 0.0001.

Recurrence was noted in 6 patients out of 83 in group A (92.7% success rate), and in 15 patients out of 41 in group B (63.4% success rate). Moreover, in 8 patients, at least 2 dilations were needed. When comparing the recurrence rate between the 2 groups using chi-square 2-way test, significant difference was obtained (χ² = 16.81, DF = 1, p < 0.0001). Therefore, other procedures were later needed in these patients in order to relief symptoms.

No significant difference was obtained between the 2 groups concerning symptom relief on patients successfully treated, using

<table>
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<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heller Myotomy (N=152)</td>
<td>Pneumatic Dilation (N=41)</td>
<td>p</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>49.1 (15.4)</td>
<td>56.6 (13.8)</td>
<td>0.0036</td>
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<tr>
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<td>51.0 [17.0, 82.0]</td>
<td>59.0 [26.0, 81.0]</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>74 (48.7%)</td>
<td>23 (56.1%)</td>
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</tr>
<tr>
<td>M</td>
<td>78 (51.3%)</td>
<td>18 (43.9%)</td>
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<tr>
<td>Hospital stay</td>
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</tr>
<tr>
<td>Mean (SD)</td>
<td>5.11 (1.95)</td>
<td>1.95 (1.85)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Median [Min, Max]</td>
<td>5.00 [2.00, 12.0]</td>
<td>1.00 [1.00, 10.0]</td>
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<tr>
<td>Preprocedural Eckardt score</td>
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<td></td>
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</tr>
<tr>
<td>Mean (SD)</td>
<td>7.1 (1.86)</td>
<td>6.68 (1.95)</td>
<td>0.2213</td>
</tr>
<tr>
<td>Median [Min, Max]</td>
<td>7.00 [4.00, 12.0]</td>
<td>7.00 [3.00, 10.0]</td>
<td></td>
</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>0.84 (1.12)</td>
<td>1.08 (0.97)</td>
<td>0.2999</td>
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<td>1.00 [0.30]</td>
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</tr>
<tr>
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<td>75</td>
<td>15</td>
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<tr>
<td>Recurrence</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>6 (7.3%)</td>
<td>15 (36.6%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>N/A</td>
<td>69</td>
<td>0</td>
<td></td>
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<tr>
<td>Esophageal perforation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>7 (4.6%)</td>
<td>1 (2.43%)</td>
<td>0.99</td>
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</table>
When evaluating the periprocedural morbidity, esophageal perforation occurred in 7 patients in group A (4.6%) and 1 patient in group B (2.43%), but with no statistically significant difference (p=0.99).

The surgical group was subdivided into 2 groups: A1 group, with robotic approach (RG - 83 patients) and A2 group, with laparoscopic approach (LG - 69 patients), as seen in (Table 2). The conversion rate in LG was 2.8% (2 patients) due to intraoperative esophageal perforation that could not be managed minimally invasive, which were excluded. No conversions were recorded in the RG. In group A1, fundoplication was performed in 69 patients (64 Dor, 2 Toupet and 3 Nissen), while in group A2 fundoplication was performed in 38 patients (36 Dor and 2 Toupet).

When comparing the total length of hospital stay, significant difference was obtained between the 2 groups, with a mean of 4.78±1.59 days in the RG, and, respectively 5.52±2.1 days in the LG (t = 2.40, DF = 124.34, p = 0.0177).

The mean operative time was slightly higher in the LG (130±41.35 minutes) than in the RG (117.5 ± 39.18 minutes), but without statistically significance (t = 1.89, DF = 141.86, p = 0.06).

Esophageal perforations were recorded in 2 patients from the RG (2.2%) and 5 patients in LG (7.2%), but without significant difference (p= 0.24).

The success rate was comparable between the 2 groups (p = 1), with 2 recurrences in the RG (6.7%), and 4 in the LG (7.5%).

No significant difference was obtained between the 2 groups concerning symptom relief on successfully treated patients followed-up using postoperative Eckardt score (t = 0.54, DF = 145, p = 0.5860).

Postoperative complications were evaluated using Clavien-Dindo classification, as it follows; in LG, 2 patients classified as Clavien-Dindo II (intrapleural abscess successfully treated with antibiotherapy, atrial fibrillation chemically converted), and 1 patient classified as Clavien-Dindo IIIa (intrapleural abscess which required percutaneous drainage along

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A1 Robotic Group (N=83)</th>
<th>Group A2 Laparoscopic Group (N=69)</th>
<th>p</th>
</tr>
</thead>
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<td>47.1 (15.4)</td>
<td>51.2 (15.3)</td>
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<td>Median (Min, Max)</td>
<td>50.0 [17.0, 76.0]</td>
<td>51.0 [30.0, 82.0]</td>
</tr>
<tr>
<td>Gender</td>
<td>F</td>
<td>43 (51.8%)</td>
<td>31 (44.9%)</td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>40 (48.2%)</td>
<td>38 (55.1%)</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>Mean (SD)</td>
<td>4.78 (1.59)</td>
<td>5.52 (2.16)</td>
</tr>
<tr>
<td></td>
<td>Median (Min, Max)</td>
<td>5.00 [2.00, 10.0]</td>
<td>5.00 [3.00, 12.0]</td>
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<tr>
<td>Operative time</td>
<td>Mean (SD)</td>
<td>117.5 (39.18)</td>
<td>130 (41.35)</td>
</tr>
<tr>
<td></td>
<td>Median (Min, Max)</td>
<td>110 [80.0, 200.0]</td>
<td>120 [90.0, 230.0]</td>
</tr>
<tr>
<td>Preoperative Eckardt score</td>
<td>Mean (SD)</td>
<td>6.43 (1.88)</td>
<td>7.87 (1.85)</td>
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<td></td>
<td>Median (Min, Max)</td>
<td>6.00 [4.00, 12.0]</td>
<td>8.00 [4.00, 12.0]</td>
</tr>
<tr>
<td>Postoperative Eckardt score</td>
<td>Mean (SD)</td>
<td>0.89 (1.13)</td>
<td>0.79 (1.12)</td>
</tr>
<tr>
<td></td>
<td>Median (Min, Max)</td>
<td>0.75 [0.30, 3.00]</td>
<td>0.75 [0.30, 3.00]</td>
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<tr>
<td>Recurrence</td>
<td>N/A</td>
<td>2 (6.7%)</td>
<td>4 (7.3%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>53</td>
<td>16</td>
</tr>
</tbody>
</table>
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with antibiotics); in RG, there were 4 patients classified Clavien-Dindo II (1 patient with hypertension crisis, 1 with urinary infection, 1 with esophageal oedema and 1 intraperitoneal collection treated with antibiotics), and 1 patient Clavien-Dindo IIIa (postoperative fistula that required esophageal stent placement in a patient with unrecognized intraoperative esophageal perforation).

Postprocedural esophagitis rates were higher in patients with no fundoplication (6 out of 37 - 16.2%) and in patients treated with pneumatic dilation (4 out of 26 - 15.4%) than in patients with fundoplication (4 out of 46 – 8.5%), as seen in (Table 3). However, significant difference was not obtained (p=0.32).

Discussion

Heller myotomy with fundoplication is currently considered by many authors the most effective treatment. However, it is difficult to prove superiority of this procedure over another because achalasia is a rare disorder and long-term outcomes are scarce. There are factors that influence the clinical results even within the same treatment method. In case of Heller myotomy, differences may result from the type of fundoplication used (partial, total, anterior, and posterior) (7). In case of pneumatic dilation those factors might be the type or diameter of balloon, the degree of balloon inflation, the duration of inflation or the need for discontinuing the balloon distension because of various reasons (8).

A newer treatment than those already discussed is per-oral endoscopic myotomy (POEM), which is not available in our center. Several studies showed promising results in terms of relieving symptoms, with a success rate comparable with PD or HM (9,10). Even though, it is considered a refluxogenic procedure, many patients developing reflux esophagitis (11). However, the long-term outcomes of this method are still under further evaluation.

Based on HRM, the Chicago classification was proposed, dividing achalasia in 3 subtypes (12). It appears that this classification might have prognostic value, several studies showing that type 1 and 2 have better outcomes with PD or HM, while type 3 is better managed with POEM (13-15).

In the present study patients with similar baseline characteristics were initially divided into 2 groups (HM and PD) and were compared. The mean age in HM group was 49 years old, while in the PD group was 56.6 years old, suggesting that the latter approach was chosen on slightly older patients. Similar to our study, Nickel et al also reported significant difference concerning the age between the 2 groups (16).

After a mean follow-up of 24 months, there were no significant differences regarding the relief of symptoms (using postprocedural Eckardt score) between group A and group B (p = 0.2999). Nickel et al reported in a study in 2019 similar results regarding the relief of symptoms between Heller myotomy and endoscopic balloon dilation after a mean follow-up of 75 months (16). Moonen et al also showed in 2015 comparable results in Eckardt score after myotomy and pneumatic dilation in a large multicenter randomized trial. The success rate was 84% after 5 years in HM group, compared with 82% in the PD group, with the mention that 25% of patients in PD group developed
recurrence and needed redilation (17).

Cheng et al reported in a meta-analysis in 2017 that short-term outcomes (at 3 months and 1 year of follow-up) were better after HM compared with PD. However, results are with no significant differences in long-term outcomes. Remission rates were comparable within 2 and 5 years (18).

In our study there was significant difference when comparing the recurrence rate between the two groups (92.7% vs. 63.4%, p < 0.0001). Moreover, in 8 patients from group B, at least 2 dilations were needed in order to relief symptoms.

Similar results were obtained by Nickel et al, because patients with PD received significantly further reinterventions than those with HM (100% vs. 10.5%) (16). Zaninotto et al concluded that HM could be a definitive treatment due the fact that 91.2% of patients have a symptom relief after 24 months with rarely need for another intervention (19). In contrast with it, multiple studies reported higher rates for repeated dilatations after PD which may lead to a higher risk for esophageal perforation (20,21).

In our study there were 7 esophageal perforations in the HM group (4.6%) versus one in the PD group (2.43%), but did not reach a statistically significant difference probably due to the sample size. Campos et al also reported in a meta-analysis that included 7855 patients, a higher rate for esophageal perforation after HM compared with PD (6.3% vs. 1.6%) (22).

The comparison between the efficacy of laparoscopic and robotic myotomy could be also difficult. The reason is an important heterogeneity among patients in some cases.

In the HM group, we compared the outcomes of patients treated by standard laparoscopic and robotic procedures. Therefore, they were subdivided into RG (A1) and LG (A2).

The success rate was comparable between the two groups, robotic and laparoscopic (93.3% vs. 92.5%). Corresponding to our study, Horgan et al reported in a multicenter study involving 121 patients that outcomes of the laparoscopic myotomy and robotic myotomy groups are comparable at 18 and 22 months, respectively (23). In other 2 studies, Sanchez et al and Perry et al provided similar results in a follow up period of 18 months and 9 years, respectively (24,25). This suggest that both approaches are effective when comparing the recurrence rate.

Regarding the relief of symptoms using the postoperative Eckardt score, Kim et al reached in a single center study significant difference in favour of the robotic approach. They reported that the reason could be a longer myotomy using the robotic procedure compared with laparoscopy (26). However, no significant difference was obtained in our study between the 2 groups concerning symptom relief using the postoperative Eckardt score (p = 0.5860).

In the present study there was significant difference in length of hospital stay, with a mean of 4.78±1.59 days in RG vs. 5.52 ±2.1 days in LG (p = 0.0177). A systematic review by Xie J et al on 3214 patients included in 7 studies showed no difference in length of stay between the 2 procedures (27).

An important difference, though not statistically significant, was observed in the operative time with a mean of 130 minutes in the LG versus 117 minutes in the RG (p = 0.06). Arcerito M et al also reported a shorter operative time with the robotic approach, with significant difference (28). However, other studies reported comparable results between the 2 procedures, but slightly in favour of laparoscopic approach (23,25,29). The differences regarding length of stay and operative time may be attributable to differences in factors such as surgeon experience or the healthcare system.

Esophageal perforation is the most common intraoperative complication when performing a Heller myotomy. The systematic review by Xie J et al reported significantly lower rates in robotic approach (27). In this study, esophageal perforation was found in 2 patients from the RG (2.2%) and 5 from the LG (7.2%). Despite the fact that there is no significant statistical difference, the lower number of perforations in the RG was provided by the technical advantages of the device.
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(facilitates muscular fiber dissection due to increased degrees of freedom of instruments and enhanced vision).

Current literature indicates that there is a higher risk of conversion to open when choosing the laparoscopic approach. Ali et al obtained a conversion rate of 5% vs 0% 30, while Kim et al showed a conversion rate of 8.6% vs 0% (26). Similar to the literature, the conversion rate in this study was 2.8% in the LG, while no conversions were recorded in the RG.

The occurrence of postprocedural gastro-esophageal reflux is described to be higher in patients treated with pneumatic dilations and in those with surgical myotomy alone (31,32). Therefore, the addition of fundoplication may lower the risk of postoperative esophagitis (33, 34). In the present study postprocedural esophagitis rates were higher in HM patients with no fundoplication (16.2%) and in patients treated with PD (15.4%) than in HM patients with fundoplication (8.5%), but without statistically significant difference.

The rate of postoperative complications requiring an intervention was not significantly different in the 2 groups. In particular, 1 patient with intraperitoneal abscess Clavien-Dindo grade IIIa needed percutaneous drainage along with antibiotics in the LG, and 1 patient Clavien-Dindo IIIa (postoperative fistula that required esophageal stent placement in a patient with intraoperative esophageal perforation) in the RG.

In general, our results are similar to previous studies with shorter or similar periods of follow-up. However, our study is nonrandomized and has some limitations. First of all, there was a relatively small number of patients enrolled. Additionally, follow-up could not be obtained for all of them, which we consider could be improved, period and methods alike, for a better understanding of this rare disease.

Conclusion

The present study indicates that surgery may be a better choice in fit patients for the treatment of achalasia. The procedure has a better success rate, even if the long-term outcomes are comparable in patients successfully treated. Concerning the minimally invasive approach chosen, the success rate and long-term results were comparable between laparoscopy and robotic surgery. Advantages were observed in the length of hospital stay and the operative time in favour of robotic approach. Even tough, considering the higher cost of robotic surgery, laparoscopic approach seems to be a feasible option for experimented surgeons.

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Author’s Contributions

The authors confirm contribution to the paper as follows: Vlad-Costin Ilie: conceptualization (lead), investigation (equal), writing - original draft (equal); Simona Manciu: methodology (lead), validation (lead), writing - original draft (equal); Monica Lacatus: resources (equal); Oana Stanciulea: resources (equal); Ovidiu Bitere: investigation (equal); Ion Bancila: resources (equal); Anca Mirela Dimitriu: resources (equal); Larisa Badea: investigation (supporting); Mircea Manuc: supervision (supporting); Catalin Vasilescu: supervision (lead), writing – review and editing (lead). Vlad-Costin Ilie and Simona Manciu share first authorship.

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The work was approved by the local ethical committee in our institute and all patient had consented to be enrolled in the study.
References


