Management of Open Tile C Pelvic Fractures and Their Outcomes: A Retrospective Study of 30 Cases

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Background: Open Tile C pelvic fractures are particularly severe. However, reports on their management and outcomes are relatively rare. This study analyzed the demographic and clinical characteristics of patients with open Tile C pelvic fractures and describes our management and outcomes of these injuries.

Methods: This retrospective review included all patients with open Tile C pelvic fractures treated in our department between January 2014 and June 2021. Data on patient demographics, characteristics of the injuries, surgical management, and outcomes were analyzed.

Results: Thirty patients with a mean age of 34.0 years met the diagnostic criteria. The average Injury Severity Score was 40.3. According to the Tile fracture classification, 6 patients sustained type C1.1, 12 sustained type C1.2, 3 sustained type C1.3, 5 sustained C2 and 4 sustained type C3. Most patients had soft tissue injuries in multiple zones. All patients sustained associated injuries. Management consisted of bed rest in 8 cases, external fixation as the final strategy in 14, conversion from external fixation to internal fixation in 3, open reduction with internal fixation in 5, and amputation in 6. The average amount of packed red blood cells transfused was 33.3 units, the average intensive care unit stay was 11.3 days, the mean number of operations required was 6.2, and the mean length of hospital stay was 81.8 days. The main complications were early soft tissue infections and venous thrombosis. One patient died of sepsis and multi-organ failure. Soft tissue injuries in multiple zones increased utilization of hospital resources whereas anorectal injuries did not. Vascular damage accompanying truck crush injuries had a high amputation rate.

Conclusion: Open Tile C pelvic fractures require multidisciplinary diagnosis and management and consume considerable hospital resources. More emphasis needs to be placed on this complex injury.

Keywords: open tile C fractures, management, outcomes

Introduction

An open pelvic fracture is a fracture of the pelvis that is usually caused by high-energy trauma and communicates directly with the rectum, vagina, or the overlying soft tissues laceration.¹,² Open pelvic fractures comprise only 2%–4% of all pelvic fractures but have a higher mortality rate than other types of pelvic fracture.³–⁶ Management of open pelvic fracture remains challenging. Moreover, an open Tile C pelvic fracture is associated with instability of the pelvic ring, which makes treatment even more difficult.⁷,⁸

Most open pelvic fractures are associated with multiple trauma involving other areas of the body, including the brain, thorax, abdomen, extremities, and other regions.⁹–¹¹ The current consensus is that management of open pelvic fractures consists of control of hemorrhage, management of soft tissues, identification and management of associated injuries, and fracture stabilization.²,¹² Early uncontrolled massive hemorrhage and pelvic sepsis are the main causes of the high
mortality rate in patients with open pelvic fracture.\textsuperscript{13,14} Adequate resuscitation and blood transfusion are essential components of early management. Colostomy and cystostomy are helpful for prevention or control of infection if anorectal and urogenital injuries are present.\textsuperscript{6,15,16} Type C pelvic fractures present with complete instability of the entire pelvic ring, which makes treatment very difficult, and maintaining the mechanical stability of the pelvis can aid in effective control of bleeding and resuscitation.\textsuperscript{17,18} However, in patients with an open Tile C pelvic fracture, it is not uncommon for the hemipelvis to be separated from the axial skeleton with irreparable avulsion or traction injury of the iliac vessels and nerves, which may result in hemodynamic instability, devascularization, and life-threatening sepsis. Early hemipelvectomy is essential in these cases after prompt assessment by an experienced surgical team.\textsuperscript{19,20}

Studies focused on the management of open Tile C pelvic fractures and their outcomes are rare. In this study, we analyzed the demographic characteristics of patients with open Tile C pelvic fractures and summarized the clinical features of these injuries and their outcomes.

Materials and Methods
A total of 1344 patients with pelvic fractures were admitted to the Shandong Provincial Hospital Affiliated to Shandong First Medical University between January 2014 and June 2021. Thirty of these patients met the criteria for open Tile C pelvic fracture and were transferred to the operating room for further treatment as soon as their vital signs and hemodynamics had stabilized in the emergency department. The study was approved by our institutional medical ethics committee. The present study conforms to the Declaration of Helsinki. All patients involved gave informed consent (the patients under 18 years of age signed the informed consent by the parent or legal guardian of patients) and all data were anonymized before the analysis to safeguard patient privacy.

The following information was collected for each patient: age, sex, mechanism of injury, Injury Severity Score (ISS), type of open pelvic fracture (include bony injury according to the Tile classification of pelvic fractures,\textsuperscript{21} soft tissue injury according to the Gustilo-Anderson classification,\textsuperscript{22} soft tissue injury zone(s) according to the systems devised by Faringer\textsuperscript{15} and Jones-Powell\textsuperscript{23} separately), associated injuries, orthopedic management for the pelvic fracture, units of packed red blood cells (PRBC) transfused during the hospital stay, length of stay in the intensive care unit (ICU), number of operations performed, complications, and total length of hospital stay.

Statistical Analysis
The results are presented as the mean ± standard deviation. All statistical analyses were performed using SPSS software version 24.0 (IBM Corp, Armonk, NY, USA). A \textit{p}-value <0.05 was considered to be statistically significant.

Results
Patient Characteristics
Thirty patients had a diagnosis of open Tile C pelvic fracture. \textbf{Table 1} shows the patient demographics, ISS data, and mechanisms of injury. The mean age was 34 years (range, 13–63). There were 18 men and 12 women. The average ISS was 40.1 (range, 29–59). Motor vehicle collision was the most common cause of injury (n=14), followed by an accident.
involving a truck (n=9). Other causes were mechanical crush injury (n=5), burns combined with a fall (n=1), and being struck by a falling object (n=1).

Classification of Open Tile C Pelvic Fractures

The open Tile C pelvic fractures are classified in Table 2. The Tile classification system is used to describe the pattern of bony injury. The most common injury pattern was type C 1.2 (n=12, combined with T-type acetabular fractures according to the Letournel and Judet classification system\(^24\) in 2 patients), followed by type C 1.1 (n=6), type C 2 (n=5), type C 3 (n=4), and type C 1.3 (n=3).

All patients were considered to be grade 3 according to the Gustilo-Anderson classification. Rectal tears or perineal lacerations with the potential for contamination were included in grade 3.

The locations of soft tissue injuries were classified according to the Faringer system. At least two zones were involved in most cases (18/30). Isolated zone I injuries were found in 8 patients, isolated zone II injuries in 2, and isolated zone III injuries in 2; 7 patients had soft tissue injuries in both zones I and II, 2 had injuries in both zones I and III, 2 had injuries in both zones II and III, and 7 had injuries in zones I, II, and III. Using the Jones-Powell classification, 6 cases were class 2 and 25 were class 3.

Most patients (24/30) sustained Jones-Powell type III soft tissue injuries and the remaining 6 had type II injuries. There were no type I injuries.

Associated Injuries

All patients sustained concomitant extra-pelvic damage, which consisted of head injuries (n=4, 13.3%), chest injuries (n=5, 16.7%), abdominal injuries (n=13, 43.3%), extremity injuries (n=12, 40%) and spinal injuries (n=5, 16.7%). Fifteen patients (50%) had a rectal injury, and all required a diverting colostomy. Fourteen patients (46.7%) had urogenital injuries involving the bladder (n=14) and/or the urethra (n=3). Primary repair was performed in 3 of the patients with

<table>
<thead>
<tr>
<th>Type</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Table 2 The Classification of Open Tile C Pelvis Fractures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tile Classification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1.1</td>
<td>6</td>
<td>20.0%</td>
</tr>
<tr>
<td>C1.2</td>
<td>12</td>
<td>40.0%</td>
</tr>
<tr>
<td>C1.3</td>
<td>3</td>
<td>10.0%</td>
</tr>
<tr>
<td>C2</td>
<td>5</td>
<td>16.7%</td>
</tr>
<tr>
<td>C3</td>
<td>4</td>
<td>13.3%</td>
</tr>
<tr>
<td><strong>Gustilo-Anderson Classification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>II</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>III</td>
<td>30</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Faringer Classification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone I</td>
<td>8</td>
<td>26.7%</td>
</tr>
<tr>
<td>Zone II</td>
<td>2</td>
<td>6.7%</td>
</tr>
<tr>
<td>Zone III</td>
<td>2</td>
<td>6.7%</td>
</tr>
<tr>
<td>Zone I&amp;II</td>
<td>7</td>
<td>23.3%</td>
</tr>
<tr>
<td>Zone I&amp;III</td>
<td>2</td>
<td>6.7%</td>
</tr>
<tr>
<td>Zone II&amp;III</td>
<td>2</td>
<td>6.7%</td>
</tr>
<tr>
<td>Zone I, II&amp;III</td>
<td>7</td>
<td>23.3%</td>
</tr>
<tr>
<td><strong>Jones-Powell Classification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>II</td>
<td>6</td>
<td>20.0%</td>
</tr>
<tr>
<td>III</td>
<td>24</td>
<td>80.0%</td>
</tr>
</tbody>
</table>
bladder injury and suprapubic drainage with delayed repair in 8. Three patients with hematuria only were treated conservatively. Surgical exploration revealed nerve avulsions in 9 patients (30%), which included lumbosacral nerve injury in 5 cases and sciatic nerve injury in 4. Discontinuity of vessels was detected in 7 patients (23.3%), and consisted of external iliac vessel injury in 3 cases, femoral vessel injury in 2, and internal iliac vessel injury in the patient who was injured by a falling object.

Management of Pelvic Fractures
The pelvic fracture was managed by bed rest in 8 of the 30 cases (23%). Fourteen patients (46.7%) were treated by external fixation as the final strategy. External fixation was performed as the first-stage of management in 3 patients (10%) and followed by internal fixation at 30 days, 3 months, and 1 week in one case each when soft tissue conditions allowed. One patient underwent open reduction with internal fixation (ORIF) at 20 days without external fixation. ORIF was performed at the time of the first operation in 4 patients (13.3%) and was combined with external fixation in 3 cases. Vascular and nerve injuries are common in patients with open Tile C pelvic fractures. Two patients underwent partial traumatic hemipelvectomy and one underwent hip disarticulation amputation in the first operation because of irreparable iliac vessel and nerve damage. One patient sustained a rupture of the femoral artery for which a vascular anastomosis was completed within 5 hours after injury. Unfortunately, this patient developed acute renal failure that did not improve on hemodialysis and underwent hip disarticulation amputation after 4 days as a life-saving measure. Two patients who also had irreparable popliteal artery damage underwent femoral amputation.

Blood Transfusion and Stay in ICU
The mean blood transfusion requirement was 33.3 units (range, 9.5–92.5) during the hospital stay (Table 3). Only one patient received less than 10 units. The average length of stay in the ICU was 11.3 days (Table 3).

Number of Operations Required and Length of Hospital Stay
Most of our patients required multiple operations, and the mean number performed was 6.2 (Table 3). The mean length of hospital stay was 81.8 days (Table 3).

Complications and Mortality
Soft tissue infections were very common in the early stages after admission. Most patients (28/30) developed culture-confirmed bacterial infections. The most common causative pathogen was Escherichia coli (n=14), followed by Acinetobacter baumannii (n=9), Pseudomonas aeruginosa (n=8), and Enterococcus faecium (n=4). Six patients were confirmed to have lower limb venous thrombosis by ultrasonography. A 63-year-old man who sustained rectal and perineal tears (Tile C1.1, Faringer zones I and II, Jones-Powell type III) died of sepsis and multi-organ failure after 126 days of treatment.

Hospitalization-Related Factors
Some hospitalization-related data (ISS, amount of PRBC transfused, length of ICU stay, number of operations required, and length of hospital stay) were analyzed. Univariate analysis identified mechanism of injury, location of soft tissue injuries, and anorectal injury status.

<table>
<thead>
<tr>
<th>Table 3 PRBCs, ICU Stay, Operation Frequency and Hospital Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics</td>
</tr>
<tr>
<td>PRBCs (units)</td>
</tr>
<tr>
<td>ICU stay (days)</td>
</tr>
<tr>
<td>Operation frequency (times)</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
</tr>
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</table>

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Truck crush involves high-energy force that can cause multiple severe injuries. Most of the patients who had sustained their injuries as a result of an accident involving a truck, except for one, had injuries in at least two zones. Therefore, we divided the patients into a truck crush injury group and an injury of other cause group and compared the ISS, ICU stay, number of operations required, and length of hospital stay between the two groups. There were no correlations between any of these parameters and cause of injury. However, there was a significant association between amount of PRBC transfused and type of injury (Table 4). It should be noted that all patients who underwent amputation had sustained a truck crush injury.

Next, we divided the patients according to the number of zones involved into an isolated zone group and a multiple zone group (Table 5). There were significant between-group differences in amount of PRBC transfused, length of ICU stay, number of operations required, and length of hospital stay (all \( p < 0.05 \)). There was no correlation of ISS or length of ICU with the location of soft tissue injuries. These findings indicate that patients with injuries involving more than two zones will have a higher PRBC transfusion requirement, need more surgeries, and have a longer hospital stay.

Anorectal injury may cause pelvic sepsis, and a colostomy and rectal washout is considered a standard of care for open pelvic fracture. Therefore, we investigated whether or not anorectal injury had an impact on our hospitalization-related data. We found no correlation of anorectal injury with the ISS, amount of PRBC transfused, length of ICU stay, number of operations required, or length of hospital stay (Table 6).

### Table 4 Hospitalization-Related Factors of Mechanism of Injury

<table>
<thead>
<tr>
<th></th>
<th>ISS</th>
<th>PRBCs</th>
<th>ICU Stay</th>
<th>Operation Frequency</th>
<th>Hospital Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Truck crush</td>
<td>40.33±2.46</td>
<td>47.78±9.63</td>
<td>15.33±5.01</td>
<td>7.44±1.14</td>
<td>81.00±11.99</td>
</tr>
<tr>
<td>Other cause</td>
<td>40.05±1.64</td>
<td>27.06±3.53</td>
<td>9.57±2.30</td>
<td>5.67±0.74</td>
<td>82.14±11.15</td>
</tr>
<tr>
<td>P</td>
<td>0.924</td>
<td>0.018*</td>
<td>0.238</td>
<td>0.212</td>
<td>0.952</td>
</tr>
</tbody>
</table>

Note: *\( p < 0.05 \).

### Table 5 Hospitalization-Related Factors of Soft-Tissue Injuries

<table>
<thead>
<tr>
<th></th>
<th>ISS</th>
<th>PRBCs</th>
<th>ICU Stay</th>
<th>Operation Frequency</th>
<th>Hospital Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated zone</td>
<td>42.17±2.46</td>
<td>19.92±2.47</td>
<td>6.33±2.08</td>
<td>3.92±0.68</td>
<td>56.08±9.04</td>
</tr>
<tr>
<td>Multiple zones</td>
<td>38.78±1.50</td>
<td>42.18±5.79</td>
<td>14.61±3.22</td>
<td>7.72±0.77</td>
<td>98.95±11.23</td>
</tr>
<tr>
<td>P</td>
<td>0.222</td>
<td>0.006**</td>
<td>0.065</td>
<td>0.002**</td>
<td>0.011*</td>
</tr>
</tbody>
</table>

Notes: *\( p < 0.05 \), **\( p < 0.01 \).

### Table 6 Hospitalization-Related Factors of with or Without Anorectal Injuries

<table>
<thead>
<tr>
<th></th>
<th>ISS</th>
<th>PRBCs</th>
<th>ICU Stay</th>
<th>Operation Frequency</th>
<th>Hospital Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anorectal injury</td>
<td>42.73±1.97</td>
<td>36.85±7.09</td>
<td>12.60±3.19</td>
<td>6.47±0.87</td>
<td>83.80±11.52</td>
</tr>
<tr>
<td>Without anorectal injury</td>
<td>37.53±1.62</td>
<td>29.70±4.18</td>
<td>10.00±3.12</td>
<td>5.93±0.94</td>
<td>79.80±12.84</td>
</tr>
<tr>
<td>P</td>
<td>0.051</td>
<td>0.393</td>
<td>0.565</td>
<td>0.680</td>
<td>0.818</td>
</tr>
</tbody>
</table>
Discussion

Open pelvic fracture is known to be a life-threatening injury. Despite advances in management, the mortality rate in patients who sustain this type of fractures remains high.1,2

Damage control in orthopaedics is deeply rooted in surgery. A multidisciplinary approach is needed from orthopaedic, general, vascular, urological, gynecological surgeons and anesthetist, as well as other members of the surgical team. The first priority in the treatment process is aggressive resuscitation measures and control of bleeding. Direct clipping of bleeding vessels, compression bandages, and external fixation are effective methods for hemorrhage control. However, angiography and embolization should be performed in patients with hemodynamic instability. Exploratory laparotomy and retroperitoneal packing are effective for filling the retroperitoneal space as is compression hemostasis for the presacral and prostate venous plexuses.18,26,27 Early appropriate management of associated anorectal, urogenital, and other injuries is needed after restoration of hemodynamic stability. Fecal diversion with a colostomy has been considered the standard of care for open pelvic fractures to avoid pelvic sepsis.28,29 However, there are some reports suggesting that this is not always necessary and may increase morbidity.30,31 Prompt administration of broad-spectrum antibiotics, adequate irrigation, and debridement of the damaged soft tissue are important. Temporary vacuum sealing drainage is usually applied if primary closure is not possible.32,33

Open Tile C pelvic fracture is the most severe form of open fracture involving the pelvis. An open Tile C pelvic fracture have the features typical of open pelvic fractures but is also accompanied by instability of the entire pelvic ring. In some cases, the hemipelvis becomes separated from the axial skeleton at the symphysis pubis and sacroiliac joint, with serious avulsion or traction injury to iliac vessels and nerves.1,9,20,34 A recent review of studies on the management and outcomes of open pelvic fractures published between 2005 and 2019 found an average ISS of 26.8, a blood transfusion rate of 79.3%, a mean ICU stay of 12.5 days, a hospital stay of 53 days, an anorectal injury rate of 32.7%, and a urogenital injury rate of 37.4%.5 However, in our study, except for a comparable length of ICU stay, these values were considerably higher. Compared with open pelvic fractures overall, open Tile C pelvic fractures tend to be accompanied by more extensive pelvic soft tissue injuries. In our study, most patients sustained injuries in more than one Faringer zone and inevitably required repeated sessions of surgical debridement to remove necrotic tissue, control infection, and promote wound coverage. Although temporary vacuum sealing had an important role in patients whose wounds are difficult to cover with soft tissue, deep soft tissue infections cannot be prevented completely by vacuum sealing after debridement, numerous of debridement in deep tissues is necessary. Meanwhile, our study findings confirm that patients with injuries involving more than two zones have a higher PRBC transfusion requirement, need a greater number of surgeries, and have a longer hospital stay than their counterparts with injuries in one isolated zone.

Fecal contamination is a major cause of pelvic floor infection. Early colostomy in patients with anorectal injury can help to decrease the risk of soft tissue infection, make treatment easier in the event that an infection does occur, make anorectal wound management easier, and allow patients to resume eating at an earlier stage. Several clinical studies have shown that selective colostomy based on the Faringer classification can reduce mortality in patients with open pelvic fractures.15,28 Jones et al have also emphasized the need for an early diverting colostomy in patients with rectal or perineal injury.25 However, recent reports suggest that routine colostomy in the setting of an open pelvic fracture is not associated with a lower incidence of infectious complications in the abdomen or pelvis.30,31 All patients who sustained anorectal injuries in our study underwent fecal diversion. However, we did not find any correlation between anorectal injury status and the ISS, amount of PRBC transfused, length of ICU stay, number of operations required, or length of hospital stay. Large-scale studies of open Tile C pelvic fractures are very difficult to perform in view of their rarity. Therefore, the current level of clinical evidence is not high. Nevertheless, multicenter prospective studies are needed in the future to assess the benefits of early colostomy in these patients.

With the rapid development of transportation and construction, truck crush injuries are now attracting more attention. The soft tissue damage associated with truck crush injury is often severe and difficult to repair and reconstruct. Nine patients in our study had been injured by an accident involving a truck. Eight of these patients sustained soft tissue injuries in multiple Faringer zones and these injuries may have been more severe and extensive than they appeared. We found no significant increase in the ISS, length of ICU stay, number of operations needed, or length of hospital stay in

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these patients but did find that they had a higher PRBC transfusion requirement. However, it should be noted that all the amputations performed in this study were in patients with truck crush injuries. In patients with truck crush vascular injuries, even if limb salvage surgery is performed in at early stage, amputation may still be required later on because of infection, embolism, or organ failure.

The treatment protocol for stabilization of Tile C pelvic fractures includes both anterior and posterior ring fixation.\textsuperscript{34,35} Unlike with closed fractures, ORIF is particularly difficult and dangerous in patients with open Tile C pelvic fractures because of the severity of the injury, location of the open wound, degree of wound contamination, and soft tissue defects. External fixation is usually the first choice for stabilization of the pelvic ring and can help to control bleeding and avoid other implant-related complications; however, external fixation has little benefit in terms of controlling the coronal rotation and vertical displacement of the pelvis.\textsuperscript{36,37} One-stage ORIF in these patients may increase the risk of infection and not be conducive to infection control. Furthermore, ideal anatomical reduction may be not effortless to achieve until obtain an excellent soft-tissue condition. According to the current literature, the treatment of choice for stabilization of open pelvic ring fractures is controversial, and it is difficult to obtain a consensus on immobilization methods for this type of injury.\textsuperscript{5,25} In our opinion, definitive fixation should be performed if the patient’s condition allows. In the early stages, all pelvic fractures should be managed based on the principle of not aggravating the original injury. For patients with mild contamination and adequate tissue coverage, limited internal fixation (with screws or a reconstruction plate) can be performed after thorough debridement and is helpful for controlling pelvic volume, restoring the pelvic sequence, and reducing tension on the soft tissue. Debridement and external fixation should be performed first in patients with extensive soft tissue contamination and poor soft tissue coverage, and whether or not secondary conversion to internal fixation is warranted depends on the condition of the soft tissues. External fixation may be chosen as the ultimate solution in some cases. All things considered, it is often difficult to strike a perfect balance between surgical safety and the desired outcome in clinical practice.

Our experience of treating patients with open Tile C pelvic fractures at our institution is that soft tissue injuries in multiple zones are common in patients with these fractures and consume a significant amount of hospital resources. Anorectal injuries are also common with this complex injury but are not associated with increased utilization of hospital resources. Patients who have sustained truck crush injuries may have severe soft tissue damage and vascular injuries that require urgent multidisciplinary evaluation. Rapid resuscitation and early amputation may improve survival. ORIF may be preferred for anatomical reduction as the first stage with excellent soft tissue condition. However, definitive fixation can be performed in individual cases if warranted by the patient’s condition.

This study has some limitations in that had a retrospective design and a small sample size. Therefore, larger multicenter studies are required in the future.

Conclusions
Open Tile C pelvic fractures are severe and require collaborative multidisciplinary diagnosis and management. In our series, patients with these injuries consumed a large amount of hospital resources. More emphasis needs to be placed on this complex injury.

Abbreviations
ISS, Injury Severity Score; PRBC, packed red blood cells; ICU, intensive care unit; ORIF, open reduction with internal fixation.

Data Sharing Statement
All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

Statement of Ethics
The experimental protocol was established according to the ethical guidelines of the Helsinki Declaration and approved by the Human Ethics Committee of Shandong Provincial Hospital Affiliated to Shandong First Medical University. Written informed consent was obtained from all study participants.
Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

All authors warrant that they have no conflict of interest in connection with this article. They have access to all the study data and take final responsibility for the decision to submit for publication.

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