Can porous tantalum acetabular cups and augments restore the hip centre of rotation in revision hip arthroplasty? Long-term results

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Abstract. Background and aim: Loss of bone stock is the main problem in revision hip arthroplasty. Porous tantalum cups and augment constructs are possible solutions. The aim of this study was to describe results at an average follow-up of 10 years using these cups. Methods: 25 patients underwent to revision hip arthroplasty with porous tantalum cups. Acetabular bone defects were classified according to Paprosky’s in type II and III. All patients were reviewed clinically and radiographically at an average follow-up of 10 years (range 8.5 to 13 years). Changes in inclination angle of the cup and position of the hip centre of rotation (COR - measured and calculated using Pierchon’s method), and possible periacetabular radiolucency lines were assessed. Results: A statistically significant improvement in Harris Hip Score and hip range of motion was observed. The hip COR had been lowered by 19.33 mm after revision and no changes in COR position had been measured at follow-up. Kaplan-Meier survivorship was 100% at an average follow-up of 10 years, considering acetabular revision for any reasons as primary endpoint. 88% of patients was satisfied. Complications were 3 dislocations, 4 asymptomatic heterotopic ossifications and 1 partial reabsorption of greater trochanter. Conclusions: Porous tantalum cups and augments can be considered a valid solution in acetabular revisions for addressing massive bone defects and restoring the hip COR. (www.actabiomedica.it)

Key words: revision hip arthroplasty, tantalum cup, bone defect, centre of rotation

Introduction

Revision hip arthroplasty is a complex orthopaedic surgery to deal with, especially for frequent coexistence of massive bone defects. The prevalence of hip revision surgery is 18% of the total number of hip prostheses in the United States (1) and 10–12% of the number of implants in the Swedish Register (2). Kurtz et al. predicted that in the United States the number of hip arthroplasty would increase by 174% by 2030, reaching a total of 572,000 operations, thus revision procedures would double by 2026 (3). Therefore, revision hip arthroplasty is a problem not to be underestimated, because of both the technical surgical difficulty and the high costs that should be supported by the healthcare system.

The only acetabular cup is revised in 60–70% of cases (4). The most common reasons are aseptic loosening, liner wear, periprosthetic fracture, infections and recurrent instability (2). Loss of bone stock is the main problem, because it can compromise primary stability and the following survivorship of the implant. Several solutions have been proposed over the years (1). Cemented cups, “jumbo” cups, oblong cups, iliac stemmed cups, reinforcement cages, associated with morcellized or structural bone grafts, are some of the possible surgical solutions that can be used.

In the last decades the so-called “open-cell” cups in tantalum or titanium have been developed. Their main characteristics are very high porosity, low modulus of elasticity (similar to cancellous bone) and high coefficient of friction on bone (5). It is also possible to
apply modular augments to fill the bone defects. Studies published in the literature are promising, but the numbers are still small with mid-term follow-up, especially for revisions with massive bone defects (5,6,7).

The aim of the present study was to describe results at an average 10-year follow-up using hemispherical highly porous tantalum cups and augments in acetabular revision surgery.

Materials and methods

Characteristics of the patients

109 consecutive acetabular revisions after total hip arthroplasty were performed in our Department from January 2008 to May 2012. 37 patients underwent revision using porous tantalum cementless hemispherical cup (Trabecular Metal Acetabular Revision Shell, Zimmer, Warsaw, Ind.). In the present study we aimed to assess only patients with severe bone defect, so we excluded 12 patients where the bone defect was classified as Paprosky’s type I. Thus, 25 patients (14 females and 11 males) were included in the study. The hip was the right side in 12 cases and the left side in 13 cases. In 44% of cases (11 cases) stem revision was performed as well, using cementless Link MP modular stem (Walder-Link GmbH, Hamburg, Germany). 5 patients underwent revision after cemented spacer removal. The mean age of the patients at the time of revision arthroplasty was 74.1 years (range 60-86 years), and the average follow-up period was 10 years (range 8.5-13 years).

Diagnosis at the time of primary arthroplasty was primary hip osteoarthritis in 17 cases (68%), avascular necrosis of the femoral head in 3 cases (12%), femoral neck fracture in 3 cases (12%) and hip osteoarthritis secondary to congenital dysplasia in one case (4%) and to hip dislocation in another case (4%).

The reasons for revision were aseptic loosening in 15 cases (60%), recurrent dislocation in 2 cases (8%), periprosthetic infection treated with 2-stage revision (cemented spacer removal) in 5 cases (20%) and the presence of pseudotumor in 3 cases (12%).

The acetabular bone defects were classified according to Paprosky’s classification in type IIA in 8 cases (32%), type IIB in 5 cases (20%), type IIC in 2 cases (8%), type IIIA in 6 cases (24%) and IIIB in 4 cases (16%) – Tab. 1.

Surgical technique

Antibiotic prophylaxis with Teicoplanin was administered preoperatively, while low-molecular-weight heparin was used in the post-operative for venous thromboembolism prophylaxis.

All surgical operations were performed via direct lateral approach with patients in supine position. In case of revision for infection, samples of periarticular soft tissues were routinely collected for cyto-histologic examination with neutrophil granulocyte count in 40 high-power fields (40x) after cemented spacer removal. The exam was considered positive for infection when 5 or more neutrophil granulocytes per field were found.

Acetabular focal bone defects were filled with morcellized bone allograft, and peripheral and central

| Table. 1 Characteristics of the patients included in the study. |
|---------------------------------------------------------------|
| **Characteristics of the patients**                           |
| **N° patients (%)**                                           |
| **Gender**                                                    |
| Male 11 (44.0%)                                               |
| Female 14 (56.0%)                                             |
| **Age (years)**                                               |
| 74.1 ± 5.7                                                    |
| **Indication to revision**                                    |
| Aseptic loosening 15 (60.0%)                                  |
| Infection 5 (20.0%)                                           |
| Instability 2 (8.0%)                                          |
| Pseudotumor 3 (12.0%)                                         |
| **Femoral stem revision**                                     |
| Revisioned 11 (44.0%)                                         |
| Not revisioned 14 (56.0%)                                     |
| **N° revisions before index revision**                        |
| 1 22 (88.0%)                                                  |
| 2 2 (8.0%)                                                    |
| 3 1 (4.0%)                                                    |
| **Paprosky’s bone defect**                                    |
| IIA 8 (32.0%)                                                 |
| IIB 5 (20.0%)                                                 |
| IIC 2 (8.0%)                                                  |
| IIIA 6 (24.0%)                                                |
| IIIB 4 (16.0%)                                                |
acetabular deficiency with modular porous tantalum augments. A thin layer of cement was applied between the cup and the augment to avoid fretting of the metallic components. As manufacturing indications, the polyethylene liner was cemented into the acetabulum, achieving a single block component, since the elasticity of the cement is similar to cancellous bone and porous tantalum (Fig. 1).

The femoral head was always replaced, and a revision uncemented femoral stem was implanted in 44% of the cases (Link MP modular stem - Walder-Link GmbH, Hamburg, Germany). Osteosynthesis of the greater trochanter was also performed in one case, using a figure of eight cerclage.

**Clinical and radiographical evaluation**

All the cases were assessed clinically and radiographically in the pre-operative, in the immediate post-operative and at an average follow-up of 10 years. The hip range of motion and the Harris Hip Score (HHS) were recorded. HHS was rated as “excellent” when it ranged between 90 and 100, as “good” between 80 and 89, as “fair” between 70 and 79 and as “poor” below 70. At last follow-up examination, the patient satisfaction level was classified in “very satisfied”, “satisfied”, “fairly satisfied” and “unsatisfied”.

In the pre-operative period, an antero-posterior radiograph of the pelvis and axial view of the hip were taken. The bone defect was defined according to Paprosky’s classification. The position of the hip centre of rotation (COR) was measured considering the centre of a circle tool made around the femoral head.

Hip and pelvis radiographs were also done in the immediate post-operative and at follow-up. The following parameters were considered on the immediate post-operative radiographs: the inclination angle of the acetabular cup (referred to the horizontal line between the distal ends of the two teardrops, or when these were not visible, between the most proximal points of the two obturator foramen); the presence of gaps on the metal-bone interface (defined as the areas where the initial direct contact between bone and acetabulum was not achieved); the position of the hip COR. The horizontal distance was defined as the distance between the COR and the Kohler’s line, and the vertical distance as the distance between the COR and the horizontal line between the more distal points of the two teardrops. The normal position of the COR was calculated using the Pierchon’s method (8) (Fig. 2) and the difference between calculated and measured COR was recorded. The COR was defined as high, when proximal to at least 35 mm compared to the line between the teardrops, as proposed by Dearborn and Harris (9).

**Figure 1.** A) The tantalum augment is fixed with two screws and bone defect is filled with morcellised bone graft. B) Cement is used between augment and cup to avoid fretting. C) The tantalum cup is press-fit and the polyethylene liner is cemented inside the cup. D) Fluoroscopy shows good fit of the trial cup after tantalum augment fixation. E) Intra-operative fluoroscopy after tantalum cup fixation. F) Immediate post-operative radiographic control after cup and stem revision.

**Figure 2.** Pierchon’s method for COR calculation: A is the vertical distance between the centre of the femoral head and the line between the two teardrops; E is the vertical distance from the teardrop line to the sacro-iliac joint; C is the horizontal distance bet between the centre of the femoral head and the teardrop; D is the horizontal distance between the two teardrops. A/E is 0.20 in male and 0.18 in female; C/D is 0.30 in male and 0.25 in female.
The following parameters were considered on the follow-up radiographs: the inclination angle of the acetabular cup; the position of the COR; the presence of radiolucency lines of at least 1 mm in the three DeLee-Charnley zones (10); the presence of iliac or ischiatic periacetabular osteolytic areas; possible fixation screws breakage.

Finally, differences of the position of the COR, the inclination angle and the presence of radiolucency lines were recorded. All the measurements were made by the same observer to avoid an inter-observer error.

The acetabular cup was considered loose when there were: migration of the acetabular component greater than 4 mm vertically or horizontally compared to the immediate post-operative radiographs; screw breakage; rotation of the acetabular cup with a difference of inclination angles greater than 5°; radiolucency lines wider than 2 mm in all three DeLee-Charnley zones (10).

All the patients signed a proper informed consent form and the research was ethically conducted in accordance with the Declaration of Helsinki.

Statistical analysis

The collected data were processed by GraphPad Prism. The survivorship of the hemispherical acetabular cup was estimated using the Kaplan-Meier survival curve, considering the interval between the index arthroplasty revision and the possible next revision, regardless of the reason for such surgery (primary endpoint), and between the index arthroplasty revision and the occurrence of radiographic signs of instability of the acetabular cup (secondary endpoint).

Comparisons were made between pre- and post-operative Harris Hip Score, the inclination angles of the acetabular cup, the position of the COR in the post-operative and at follow-up examination, and the position of the hip COR measured on the radiographs compared to that calculated applying the Pierchon’s method (8). Because these variables presented a normal distribution (assessed with the Shapiro–Wilk test of normality), such comparisons were verified through the two-tailed non-parametric test devised by Wilcoxon, assuming as statistically significant a value of p below 0.05.

Results

Clinical assessment

All 25 patients were evaluated at an average follow-up of 10 years (range 8.5-13 years). The pre-operative Harris Hip Score was 39.90 ± 11.98 (range 25-78). At the most recent follow-up examination the score raised to 91.05 ± 7.65 (range 74-100, p < 0.0001). In particular, the result was “excellent” (between 90 and 100) in 16 cases, “good” (between 80 and 89) in 5 cases, and “fair” (between 70 and 79) in 4 cases. A score below 70, considered “poor”, was not recorded for any of the patients.

As regards the level of patient satisfaction, 72% of the patients (18 cases) declared to be “very satisfied”, 16% “satisfied” (4 cases), 8% “fairly satisfied” (2 cases), and 4% “unsatisfied” (1 case) – Graph. 1. The hip range of motion improved in all the patients (the results are described in Graph. 2).
Periacetabular gaps were observed on the immediate post-operative radiographs in 7 cases: the gaps resulted in DeLee-Charnley zone 1 in 1 case, in zone 2 in 4 cases, and in zone 3 in 2 cases. In all cases these gaps were not visible anymore at the follow-up radiographs, and no radiolucency lines were reported. An increase in periacetabular radiopacity was appreciated in 13 cases (52%).

The mean inclination angle of the acetabular cup measured on the immediate post-operative radiograph was 43.57° ± 9.59° (range 30°-79°). No statistically significant changes of the inclination angle were appreciated at follow-up (43.91° ± 10.38°, range 30°-80°, p > 0.50). Neither periacetabular radiolucency lines nor periacetabular osteolysis nor screw breakage nor changes in position of the hip COR were found.

The pre-operative radiographs showed a COR at a mean horizontal distance of 41.57 mm ± 10.04 mm from the Kohler’s line (range 24-75 mm), and a mean vertical distance of 38.46 mm ± 10.27 mm from the teardrop (range 10-72 mm). On the immediate post-operative radiographs, the mean horizontal distance was 37.30 mm ± 5.63 mm (range 24-52 mm) and the mean vertical distance was 19.13 mm ± 7.32 mm (range 10-38 mm). No statistically significant changes of those distances were appreciated at follow-up radiographs (mean horizontal distance 37.83 mm ± 5.84 mm and mean vertical distance 19.17 mm ± 7.23 mm, p > 0.05). The hip COR was significantly lowered by a mean of 19.33 mm (p = 0.0008) – Figs. 3, 4.

In only two cases the new COR was considered slightly higher (38 mm and 35 mm), since it presented a vertical distance that was slightly over 35 mm to the line between the two teardrops (criteria proposed by Dearborn and Harris (9) – Fig. 5).

The calculated COR (applying Pierchon’s method (8)) resulted in a horizontal distance of 36.39 mm ± 3.69 mm (range 30.75 – 42.90 mm) and in a vertical distance of 14.08 mm ± 2.44 mm (range 9.9 – 21.0 mm). The Wilcoxon test did not evidence any significant statistical difference in the horizontal distance (p = 0.13), while the 5.22 mm difference between the calculated and measured vertical distance was statistically significant (p = 0.0001). These results are described in Tab. 2.

**Complications**

No perioperative cardiovascular or thromboembolic complications were registered, as well as no infections and no periprosthetic fractures.

The occurred complications were recurrent dislocations (12%), heterotopic ossifications (16%) and a partial reabsorption of the greater trochanter (4%).
particular, 3 patients (12%) had a dislocation in the first months after surgery (one patient dislocated twice in the first two months and the other two once in the first month). Revision surgery was necessary to replace the femoral head and polyethylene liner in the first case (Fig. 6).

As regards heterotopic ossifications, 3 cases were classified as Brooker’s type 1 and one case as Brooker’s type 3. In this last patient the range of motion of the hip at follow-up examination, albeit without pain, was slightly reduced (flexion 70°, abduction 20°, adduction 30° and few degrees of rotation) and the patient complained about partial functional limitation.

Survivorship curve

The survivorship of the porous tantalum cups, applying the Kaplan–Meier survival curve, was 100% at an average 10-year follow-up considering acetabular revision for any reasons as primary endpoint.

Discussion

Nowadays revision hip arthroplasty is becoming a more and more common surgery, given the ageing of the population and the increasing number of primary implants (3). The acetabular component is the most frequently revised and the cup loosening is often associated with important osteolysis and acetabular demolition (4).

Therefore, the most commonly encountered difficulties in this type of surgery are related to bone defect management in order to achieve good primary stability of the cup. In fact, micromotions at bone-cup interface less than 40-50 μm are important to promote osteointegration (6).

Restoration of the proper hip COR is another target of revision surgery. Both very high hip COR and super-lateral COR increase the micromotions at the bone-cup interface by 13% in comparison to anatomic position and are associated with higher incidence of aseptic loosening (11).

It is easy to understand that those problems are most commonly found when the contact area between bone and acetabular cup is less than 50%. The surgical solutions that can be adopted are many and based on the residual bone stock.

Although there are good results using porous tantalum cups in Paprosky’s type I focal bone defects (12,13), traditional porous coated hemispherical cups with or without fixation screws are still a good choice.

Table 2. The hip centre of rotation (COR) and the inclination angle of the cup. The COR was measured on the radiographs in the pre-op, in the immediate post-op and at follow-up and it was calculated according to Pierchon’s method. The COR was lowered by 19.33 mm; the difference between measured COR and calculated COR at follow-up was 5.22 mm. Statistically significant differences are identified by * and **.

|                      | Pre-op COR | Immediate post-operative | Follow-up |
|----------------------|------------|--------------------------|-----------|
|                      |            | Corridor                  |           |
|                      |            | Horizontal distance       | 41.57 mm ± 10.04 mm | 37.30 mm ± 5.63 mm |
|                      |            | Vertical distance         | 38.46 mm ± 10.27 mm * | 19.13 mm ± 7.32 mm * |
|                      |            | Inclination angle of the cup | 43.57° ± 9.59° | 43.91° ± 10.38° |
|                      |            | Measured COR              |           |
|                      |            | Horizontal distance       | 37.30 mm ± 5.63 mm | 37.83 mm ± 5.84 mm |
|                      |            | Vertical distance         | 19.13 mm ± 7.32 mm * | 19.17 mm ± 7.23 mm ** |
|                      |            | Calculated COR            |           |
|                      |            | Horizontal distance       | 36.39 mm ± 3.69 mm | 36.59 mm ± 3.46 mm |
|                      |            | Vertical distance         | 14.08 mm ± 2.44 mm | 13.95 mm ± 2.90 mm ** |

Figure 6. A) Paprosky’s IIIB bone defect. B) Revision with a tantalum cup. C) Dislocation one month after the revision.
In fact, no superiority with porous tantalum cups has been demonstrated by comparison with porous-coated cups, although with the latter, cases of aseptic loosening due to periacetabular osteolysis are described in the literature (11% at 5-year follow-up) (14). This might be related to both back side wear and high mechanical stiffness of the material. However, it should be emphasized that porous tantalum cups have particular mechanical characteristics: the modulus of elasticity is very close to cancellous bone and much lower than titanium or chrome-cobalt (5). This should allow reducing periacetabular bone reabsorption due to stress-shielding, observed with stiffer cups.

Several solutions might be used in Paprosky’s type II and III bone defects. Cemented cups are associated with higher incidence of aseptic loosening, especially in younger people. Sternheim et al. reported a survivorship of 36% at 20 years in revision hip arthroplasty with cemented cups (15).

“Jumbo” cups do not restore the bone stock and they are often associated with high risk of dislocation (8–11%), due to big soft tissue detachment and to possible impingement with greater trochanter (9). The bone defect can be filled with cement (using cemented cups or the “reinforced cement under pression technique” described by Garosi et al. (16), with structural or morcellized bone graft or with modular augments. Both cemented cups and Garosi’s technique are indicated only in patients with low functional level or in younger patients with several comorbidities that can alter the graft integration, like renal or kidney transplantation, severe renal dysfunction, severe compromised microcirculation.

The most common complication reported with bone graft is the graft reabsorption, with subsequent cup loosening. This is described especially when the residual bone stock is less than 40% of the cup and a reinforcement cage does not protect the graft. Pollock et al. reported 59% of cup migration and 30% of revision at 2-year follow-up in 23 cases with massive bone graft (17).

Reinforcement cages can protect the bone graft, distributing the load on a big area (“snowshoe effect”). In this way bone stock restoration is possible. Results at 13–15 years are fairly good (survivorship of 72–78%), although frequent failures with flanges or screws breakage due to lack of osteointegration and technical difficulty of implantation were reported (18).

In the present study relatively new cups have been reviewed: hemispherical porous tantalum cups. These cups have very interesting mechanical properties that might improve the survivorship of the implant achieved with the above-described solutions, decreasing the complication rate described with other techniques. In fact, they have a very high porosity (75–80%), higher than porous-coated cups and porous titanium cups currently on the market (65–67%), in order to improve osteointegration. They have very high coefficient of friction on bone, that also allows high primary stability for bone-cup contact area of less than 30%, with a very low modulus of elasticity, close to cancellous bone (6). Given their high porosity, they can potentially work as an osteoconductive scaffold. In addition, porous tantalum modular augments, fixed with screws to the residual bone, can be used to fill the bone defect. All these features allow to avoid the use of structural bone grafts or reinforcement cages. This reduces the risk of cup loosening due to graft reabsorption; it avoids large periacetabular soft tissues detachment required for reconstruction cage positioning and it decreases technical difficulties and possible complications associated with screws and fins placement in a weakened and remodelled bone. Furthermore, augment modularity permits to fill the bone defect, to give primary stability to a hemispherical cup and thus to restore the correct position of the hip centre of rotation, also in Paprosky’s type IIIA or IIIB, that might be associated with pelvic discontinuity (1,6,12).

Although the relatively small sample, this study supported all these aspects and allowed to state that these cups seem to be a valid and effective surgical choice in acetabular revisions. In fact, in these 25 cases, no cases of aseptic loosening, screw breakage or periacetabular osteolysis were found. Particularly, in the 10 cases of Paprosky’s type III defect (6 cases of type IIIA and 4 type IIIB), no cup migration was observed at an average follow-up of 10 years. These results were consistent with other studies published in the literature (5,6,7,13). Few cases of aseptic loosening using highly porous tantalum cups are described. Del Gaizo et al. (19) reported a prevalence of aseptic loosening of 2.7% at minimum 2-year follow-up in 37 revisions.
characterized by Paprosky's type IIIA bone defect. Fernando-Fairen et al. do not observed any loosening in 263 revisions at 6 years (20). Bruggemann et al. reported 3 cases of tantalum cup revisions out of 111 at 6-year follow-up (21).

As regards the clinical assessment, all patients in the present study showed an improvement in Harris Hip Score, with “excellent/good” scores in 84% of cases; 88% of the patients defined themselves as completely satisfied with the operation. 2 out of the 3 patients who were poorly satisfied, even if they had a fair hip range of motion, were those patients who had post-operative dislocation and reported some limitations in their daily activities.

As regards osteointegration, all small periacetabular gaps, visible in the immediate post-operative radiographs, completely disappeared at follow-up radiographs, suggesting that bone could have grown in the gaps. Thus, no radiolucency lines had been reported. In addition, although no objective measurement of periacetabular radiodensity had been performed, an increase in periacetabular radio-opacity was observed in 52% of cases.

In addition to bone defect management, COR restoration is another goal to be achieved. In the present study the vertical distance was restored in 23 cases (92%). The COR was significantly lowered by an average value of 19.33 mm. However, in the two remaining cases, the pre-operative COR was very high (62 and 72 mm over the inter-teardrop line) and the distance achieved after the operation was acceptable (38 and 35 mm, respectively). Analysing the mean values, a normal position was obtained in the post-operative with a horizontal distance of 37.83 mm and a vertical one of 19.17 mm from the teardrop. These distances were similar to those calculated with Pierchon’s method and they did not change at the follow-up. In the present study porous tantalum cups and modular augments allowed to restore the COR without structural bone grafts, and no cup migration had been observed.

As regards the complications, dislocations occurred in 12% of patients (3 hips). They happened in the first two months after surgery. In only one case it was necessary to proceed with a further revision, replacing femoral head and liner. This finding was not surprising if we consider that in those 3 patients that revision was the second or third operation and there were a pseudotumor. In the literature, pseudotumor is linked to a greater incidence of dislocation, because of severe soft tissues damage (22). The prevalence of dislocations in this study was in line with several reports published in literature with different cups. Lachiewicz et al. reported a prevalence of 15% in a group made of 48 revisions with tantalum cups (12). Jones et al. described a prevalence of 10.2% on 211 revisions with cemented cups and structural bone grafts (4).

Finally, the present study had some limits. The relatively low sample size (25 revisions) and its retrospective design do not allow to affirm the superiority of these tantalum cups in comparison to others, but the assessment of a group of Paprosky’s type II and III at long-term follow-up can be considered a point of strength in their favour.

Some Authors expressed some concerns about these cups (21). Their removal for periprosthetic infection can be very difficult because of their high porous surface, and modular augments do not allow bone stock restoration. In Paprosky’s type III partial or complete reabsorption rate of bone graft is very high. Lee et al. observed that only 17.5% of structural allografts had not reabsorbed at 7-year follow-up, when bone loss was between 30% and 50% of the acetabulum (23). Maybe, as suggested by some Authors (20), structural bone grafting should be used in very young patient, where bone stock restoration and preservation are a priority for future revision.

Although the limitations, the results described in the present study are very encouraging. In fact, porous tantalum cups seem to be a valid solution even in massive acetabular defects, such as Paprosky’s type IIIA and IIIB, where traditional hemispherical cups could not be easily used. Further studies with much longer follow-up will be necessary in the future.

**Conflict of Interest:** Each author declares that he or she has no commercial associations (e.g. consultancies, stock owner-ship, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article. All patients provided written informed consent to participate in this study. The study was conducted under the principles of the Declaration of Helsinki and it does not need the ethical committee approval because of its observational retrospective design. Data have been collected from existing medical records and all patients underwent the normal clinical assessment provided by our Department.
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Received: 15 November 2021
Accepted: 23 December 2021
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