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PLATELET RICH PLASMA: A NOVEL SOLUTION FOR POST-CANAL WALL DOWN MASTOIDECTOMY COMPLICATIONS

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ABSTRACT

Background: A canal wall down mastoidectomy is a very effective technique forthe Article History: Received 4th May, 2021 eradication of advanced chronic otitis media or cholesteatomas. The advantages of canal Received in revised form 25th wall down mastoidec-tomy include excellent exposure and low rates of residual and June. 2021 recur-rent disease. However, this widely practiced technique of open cavity Accepted 18th July, 2021 mastoidectomy carries the potential of unhealedcavity. Wound healing is a complex Published online 28th August, 2021 process and healing of acute and chronic wounds can become impaired by different factors. Platelet rich plasma (PRP) is considered to be an advanced wound therapy for acute and chronic wounds. Key words: Patients and Methods: This is a prospective non randomized study which enrolled unsafe Key Words: canal wall down mastoidectomy, chronic suppurative otitis media patients attending the ENT outpatient clinics of the cholesteatoma, platelet rich plasma, otorrhea, Fayoum University Hospital. Fifty patients were scheduled for one canal wall down cavity obliteration, wound healing. mastoidectomy and were divided into two equal groups: Group A, the radical cavity, at the end of the operation, was filled with gel foam soaked with PRP. Group B, the radical cavity, at the end of the operation, was filled with only gel foam without PRP. Preoperatively, every patient was asked to rate and complete the Chronic Otitis Media Questionnaire-12 (COMQ-12). Patients were followed up to evaluate the mastoid cavity healing one month post-operatively through: clinical examination, Bates-Jensen wound assessment tool, and (COMQ-12). Results: according to COMQ-12, PRP group demonstrated a statistically significant difference as regards discharging from ear, having smelly ear and discomfort in ear in comparison to NON-PRP group (P-value <0.0001). According to the wound assessment tool, PRP group demonstrated a statistically significant difference as regards exudate amount, epithelialization, granulations and skin color surrounding the wound with rapid healing in comparison to NON -PRP group (P-value <0.0001). Conclusion: Platelet rich plasma is a cheap and cost effective platelet concentrate with enriched growth factors. It accelerates wound healing following canal wall down radical mastoidectomy.

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INTRODUCTION

A canal wall down (CWD) mastoidectomy is a very effectivetechnique for the eradication of advanced chronic otitis media or cholesteatoma. The advantages of CWD mastoidectomy include excellent exposure for disease eradication and postoperative monitoring, and low rates of residual and recurrent disease. However, this widely practiced technique of open cavity mastoidectomy carries the potential complication of unhealed cavity resulting in a chronically discharging ear. The incidence of unhealed cavity ranges between 10 and 60% (Palva 1973, Sade *et al.* 1982, Beales and Hynes 1958).

A significant number of patients have a discharging mastoid cavity, which is distressing and predisposes them to recurrent infections that may lead to further complications. These cavity problems can be managed to some extent by regular follow-up and adequate aural toilet. But, there still remains the risk of complications and a negative effect on the patient's quality of life (Mills and Phil 1988, Males and Grey 1991).

Wound healing is a complex and dynamic process (Mast 1992). Once a wound begins healing, normally the process resolves with complete wound closure. However, healing of acute and chronic wounds can become impaired by patient factors (comorbidities) and/or wound factors (infection) (Lawrence 1992).

Platelet rich plasma (PRP) is considered to be an advanced wound therapy for acute and chronic wounds. For more than

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20 years, PRP has been used to stimulate wound healing. Autologous PRP consists of cytokines, growth factors, chemokines, that promote healing (Frykberg *et al.* 2010, Reese 2010).

The mechanism of action for PRP is thought to be through the molecular and cellular induction of normal wound healing responses similar to that seen with platelet activation (Reese 2010).

The aim of this study was to evaluate the effect of PRP on the healing of the radical cavity and the complicating postoperative ear discharge after canal wall down mastoidectomy.

PATIENTS AND METHODOLOGY

This was a prospective non-randomized study, which enrolled unsafe chronic suppurative otitis media patients attending the ENT outpatient clinics of the Fayoum University Hospital. Patients were subjected to history taking, endoscopic ear examination, CT scans, and pure tone audiometry. After selecting those patients with extensive cholesteatoma, 50 patients were scheduled for one kind of surgical technique, which was canal wall down mastoidectomy, and were divided into two equal groups:

Group A: the radical cavity, at the end of the operation, was filled with gel foam soaked with PRP.

Group B: the radical cavity, at the end of the operation, was filled with only gel foam without PRP.

Inclusion criteria

Age between 10-60 years.

Exclusion criteria

- Patients with factors that would affect wound healing like diabetes mellitus and malignancy.
- Patients were excluded if they were less than 10 years of age as they would not be cooperative for questionnaire assessment; patients above 60 years of age were also excluded due to senile decline of healing power.
- Patients with previous ear operations.

Pre-operatively, every patient was asked to rate and complete the Chronic Otitis Media Questionnaire-12 (COMQ-12) (John, 2016).

Procedure

Under general anesthesia, at the start of the canal wall down operation, PRP was prepared by taking 5 cc of autologous blood from the patient, which was processed using a laboratory centrifuge (Heraeus labofuge 200, Germany). CWD mastoidectomy was started by making a postauricular incision, that was carried out along the hairline and extended inferiorly and behind the mastoid tip into a crease of the skin. The skin incision was made posterior enough to avoid the incision lying over the exenterated mastoid bone.

Mastoidectomy was carried out by wide removal of bone from the zygomatic arch to the middle fossa dura, the sinodural angle, the sigmoid sinus, and the digastric muscle. The stylomastoid periosteum was followed to the stylomastoid foramen. Removal of the bridge and lowering of the facial ridge were performed with burrs and suction-irrigation from both ends. The bone was removed until the nerve became visibleunder the last eggshell of bone. Complete removal and exenteration of cholesteatoma and all infected air cells was performed.

PRP preparation

- Whole blood (WB) was obtained by venipuncture and was collected in acid citrate dextrose (ACD) tubes.
- The blood was notchilled at any time before or during platelet separation.
- The blood was centrifuged using a 'soft' spin.
- The supernatant plasma containing platelets was transferred into another sterile tube (without anticoagulant).
- The tube was centrifuged at a higher speed (a hard spin) to obtain a platelet concentrate.
- The lower 1/3rd was PRP and upper 2/3rd was plateletpoor plasma (PPP). At the bottom of the tube, platelet pellets were formed.
- PPP was removed and the platelet pellets were suspended in a minimum quantity of plasma (2–4 mL) by gently shaking the tube.
- A layout of gel foam soaked with PRP was placed in the mastoid cavity after radical mastoidectomy in patients of group A.

Patients were followed up to evaluate mastoid cavity healing one month post-operatively through:

- 1. Clinical examination.
- 2. Bates-Jensen wound assessment tool (Bates and Sussman, 2012)
- 3. Chronic otitis media questionnaire 12(COMQ-12).

According to the follow-up results, data were statistically analyzed.

The collected data were organized, tabulated, and statistically analyzed using SPSS software statistical computer package version 22 (SPSS Inc, USA). For quantitative data, the mean, median, standard deviation (SD), and range were calculated. Kolmogorov-Smirnov test (KS) test was performed as a test of normality; an independent t-test was used to compare the two groups in regards to age.

For other variables, the Mann-Whitney-U test was used as a test of significance to compare the two groups. Within each group, the Wilcoxon-signed rank test was performed to compare between values of study variables before and after treatment. Qualitative data were presented as numbers and percentages; the chi square (χ^2) test was used as a test of significance. For interpretation of the results of the significance tests, significance was adopted at P \leq 0.05.

RESULTS

This was a non-randomized prospective controlled study. It included patients presenting to the Otolaryngology outpatient clinic of Fayoum University Hospital with unsafe ear indicated for canal wall down operation.

The sample size included patients with unsafe ear, and this size was calculated using G power 3.0.10; a minimal sample size of patients was needed to ensure power of 0.8, an alpha level of 5% and an effect size of 25. A final sample sizewas increased by 10% to overcome problems of loss to follow-up.

The study population included 50 patients with unsafe chronic suppurative otitis media and all patients were scheduled for

one type of surgical technique, i.e., canal wall down mastoidectomy. The enrolled patients were divided into two equal groups:

Group A: before closure of the wound at the end of CWD, the radical cavity was filled with gel foam mixed with PRP.

Group B: the radical cavity was filled with gel foam without PRP.

According to the follow-up results, data were statistically analyzed with a comparison between the two groups in regards tochronic otitis media questionnaire -12(COMQ-12) items (discharge from ear, smelly ear, discomfort in the ear) and Bates-Jensen wound assessment tool items (exudate amount, skin color surrounding the wound, granulations and epithelialization).

A comparison between the two groups with respect to discharge from ear: Table (1)

In the PRP group, there were statistically significant differences between patients with pre- and post-operative discharging from the ear (P < 0.0001).

In the non-PRP group, there were statistically significant differences between patients with pre- and post-operative discharge from the ear (P<0.0001).

There was statistically significant difference between the two groups in regards to post-operative ear discharge (P < 0.0001).

A comparison between the two groups with respect to smelly ear: Table (2)

In the PRP group there were statistically significant differences between patients with pre- and post-operative smelly ear (P<0.0001).

In the non-PRP group, there were statistically significant differences between patients with pre- and post-operative smelly ear (P < 0.0001).

Also, there was a statistically significant difference between the two groups (P<0.0001).

A comparison between the two groups with respect to **discomfort in the ear:** Table (3)

In the PRP group, there was a statistically significant difference between patients with pre- and post-operative discomfort in the ear (P < 0.0001).

In the non-PRP group, there was a statistically significant difference between patients with pre- and post-operative discomfort in the ear (P < 0.0001).

There was a statistically significant difference between the two groups regarding post-operative discomfort in the ear (P<0.0001).

A comparison between the two groups of the study with respect to **exudate amount:** Table (4)

There existed a significant difference between the two groups with respect to post-operative exudate amount (P < 0.0001).

A comparison between the two groups with respect to the **surrounding skin color:** Table (5)

There was a significant difference between the two groups in post-operative surrounding skin color (P < 0.0001). A comparison between the two groups with respect to **granulation:** Table (6)

There was a significant difference between the two groups in post-operative granulations (P<0.0001).

A comparison between the two groups with respect to **epithelialization**: Table (7)

There was a significant difference between the two groups in post-operative epithelialization(P<0.0001).

In group **A**, where 25 patients received PRP post-CWD, 22 had complete healing, two patients had partial healing, and one case had poor healing. In group **B**, out of 25 patients, there were 11 patients with partial healing and 14 patients with poor healing.

DISCUSSION

The purpose of surgical treatment for cholesteatoma is to eradicate the disease and prevent its recurrence. Canal wall up (CWU) mastoidectomy preserves the posterior canal wall; however, the recurrence rate is very high (36%) in adults and in children (67%) (Shohet *et al.* 2002).

In canal wall down mastoidectomy, the posterior meatal wall (PMW) is removed, providing exposure of the entire attic and middle ear, which ensures complete disease eradication. The recurrence rate is as low as 2% for this procedure. However, CWD mastoidectomy has many drawbacks, such as cavity problems (chronic otorrhea, granulations, and accumulation of debris in the exteriorized mastoid cavity requiring periodic cleaning) (Palva *et al.* 1987- Babighian 2002).

The frequency of "wet" ears is greater with canal wall down than with canal wall up mastoidectomies (Harkness *et al.* 1995). Variation in the quality of healing in mastoid cavities has never been clearly understood (Rambo 1979).

Wound healing is a natural response to tissue injury, and involves a complex cascade of overlapping cellular events. However, in order to simplify the process, it has been traditionally explained as a series of four phases: hemostasis, inflammation, proliferation, and maturation. These stages may vary in length, due to different pathologic factors, such as infection, malnutrition, venous insufficiency, ischemia, and exogenous factors (Schreml *et al.* 2010).

To overcome these disadvantages of the operated mastoid cavity following CWD (chronic otorrhea, granulations, and accumulation of debris in the exteriorized mastoid cavity requiring periodic cleaning), various mastoid space obliteration techniques can be employed. A variety of techniques have been described to obliterate the residual mastoid cavities, such as the use of muscle, cartilage, titanium, hydroxyl apatite, and bioactive glass.

A study by Mohamed *et al.* performed single stage canal wall down mastoidectomy with reconstruction of the canal wall, with partial removal of the posterior canal wall, followed by canal wall defect reconstruction. It was found that that approach restored the normal anatomy and avoided the complications of CWD. This study revealed that the mean \pm SD of healing time was 7.5 \pm 2.3 (range, 4–14) weeks. Nearly 84.2% of the patients were followed up and had dry healthy ears (Mohamed *et al.* 2017).

A study done by Ho *et al.* employed canal reconstruction and mastoid obliteration using floating cartilages and musculoperiosteal flaps to reduce mastoid cavity-associated problems secondary to canal wall down mastoidectomy. The

surgical procedure included canal wall reconstruction using free-floating cartilages and double musculoperiosteal flaps. The results and long-term follow-up demonstrated gradual widening of the neo-external auditory canal (EAC) in 18 patients (54.5%), but normal contour of the neo-EAC in the other 13 patients (39.4%). In just one case did the neo-EAC become extremely widened (Ho *et al.* 2017).

In a comparative study done by Sanjay *et al.*, the surgical outcome of mastoid cavity obliteration using bone dust versus open cavity in canal wall down mastoidectomy revealed that the incidence of ear discharge and wax formation was markedly reduced in obliterated cavities as compared to the open cavity procedure. Healing of the cavity as evidenced by early epithelialization at the end of 3 months was better in those ears where cavity was obliterated (95%) as compared to those left unobliterated (75%) (Sanjay *et al.* 2018).

A study done by Abdelrahman *et al.* using bioglass for obliteration of mastoid cavity after canal wall down mastoidectomy revealed that ear discharge was found in 90% of patients preoperatively and was found only in 15% of patients postoperatively (Abdelrahman *et al* 2014).

A study done by Munjal *et al.* used hydroxyapatite granules for mastoid cavity obliteration; it included 25 cases. Porous hydroxyapatite, which is an osteogenic bone analogue, was used to achieve reduction in mastoid bowl size and decrease cavity problems. This study revealed that complete epithelization with absence of discharge was seen in 21(84%) cases with no other cavity problems (Munjal *et al.* 2004).

A study done by Sudhoff *et al.* for posterior canal wall reconstruction using a composite cartilage titanium mesh graft in canal wall down tympanoplasty and revision surgery for radical cavities revealed that all patients maintained a normal contour of the external ear canal, without depression, extrusion, or infection. There were no failures; the study recruited short-term post-operative controls. However, the two procedures had to be revised due to incomplete coverage of the titanium mesh (Sudhoff *et al.* 2006).

Although these techniques offer the major advantage of eliminating the cavity problem, there can be long-term complications. For example, some of the obliterated tissues can shrink over time, minimizing the effectiveness of the mastoid obliteration. Additionally, the materials can become infected postoperatively, and revision surgery can damage normal structures due to obliteration of anatomical landmarks (Roberson *et al.* 2003, Bernardeschi *et al.* 2015).

Recently, a study has been done by Mohammad *et al.* to prevent granulation tissue formation and to accelerate epithelialization of the mastoid cavity in canal wall down mastoidectomy by using amniotic membrane (AM) as a biologic dressing that contains many growth factors. The use of AM post-CWD mastoidectomy is beneficial in minimizing postoperative epithelialization time. In the AM group, duration of complete epithelialization of the cavity was 41.4 ± 7.7 days, whereas in the control group it was 59.2 ± 9.1 days. Duration of time for complete epithelialization in the AM group was shorter than in the control group, which was significant (P<0.0001) (Mohammad *et al.* 2019).

To reduce mastoid cavity-associated problems secondary to canal wall down mastoidectomy, this study introduced a new procedure by using plateletrich plasma after CWD mastoidectomy in order to improve healing of the radical cavity and overcome the problems inherent to the procedure.

PRP is rich in growth factors; each growth factor activates one or several response pathways, which depend on the cellular environment. Once the growth factor has bound to a cellsurface receptor, a second messenger cascade is triggered and the signal transmission remains active, even when growth factors disappear. Depending on the growth factor, a specific group of proteins is phosphorylated and a modification in cell activity takes place. Considering that PRP is a source of growth factors, it consequently has mitogenic, angiogenic, and chemotacticproperties that promote healing and accelerate epithelialization.

A literature review reveals no reports on using PRP to promote healing after canal wall down mastoidectomy. To the best of our knowledge, this is the first study conducted to detect the effect of PRP on healing of the mastoid cavity and minimizing the postoperative problems after CWD.

The outcomes of the study were assessed using the chronic otitis media questionnaire -12(COMQ-12) and clinical examination using Bates –Jensen wound assessment tool (BWAT), one month after operation.

In this study, according to COMQ-12in the PRP group, there were statistically significant differences in regards to discharge from ear, smelly ear, and discomfort in the ear in comparison to the non-PRP group (P<0.0001). According to the wound assessment tool, in the PRP group there were statistically significant differences in regards to exudate amount, epithelialization, granulations, and skin color surrounding the wound with rapid healing in comparison to the non-PRP group (P<0.0001).

In the PRP group, out of 25 patients receiving PRP post-CWD, 22 patients had complete healing, two patients had partial healing, and in one case there was poor healing. In the other group (non-PRP), out of 25 patients, there were 11 patents with partial healing and 14 patients with poor healing.

Hence, application of PRP at the end of canal wall down operation promotes and accelerates healing and epithelialization of the cavity with a reduction of ear discharge and recurrent infection.

CONCLUSION

Platelet rich plasma is a cheap and cost effective platelet concentrate with enriched growth factors. It accelerates wound healing following canal wall down radical mastoidectomy. It minimizes mastoid cavity problems, such asotorrhea and recurrent infection, and decreases the burden on patients who have undergone CWD. It has no noticeable side effects. Further studies are recommended to evaluate the effect of application of PRP more than once to improve the poor results for cases with poor healing.

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