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Manuscript ID ZUMJ-1910-1596 (R1) 10.21608/zumj.2020.18432.1596 DOI **ORIGINAL ARTICLE** 

## **Role of Carboxymethyl Cellulose versus Vinyl Gloved Merocel Packing in Surgical Outcome of Chronic Rhinosinusitis**

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#### ABSTRACT \*Corresponding author: Background: Functional endoscopic sinus surgery (FESS) is one of the Maisoun Abdelmeged Mohamad Gabbasa most frequently performed operative procedures in the head and neck field. Faculty of Medicine, Tripoli University, It has become a standard therapy for chronic rhinosinusitis (CRS) including Libya nasal polyposis that is refractory to conservative measures. Aim of the work: The aim of the study was to compare the outcome of dissolvable E-mail:maisongabbasa@gmail.com carboxy-methylcellulose (CMC) and vinyl gloved Merocele packing in functional endoscopic sinus surgery (FESS) in adult patients. Methods: This prospective, randomized controlled trial study included 26 consecutive adult patients with a diagnosis of CRS with or without polyposis undergoing bilateral FESS, who admitted to the Otorhinolaryngology Head and Neck Outpatients Clinic, Faculty of Submit Date 2019-10-20 Medicine, Zagazig University Hospital during the period from December **Revise Date** 2020-01-05 2017 to December 2018. Results: There were statistical significance difference between CMC and 2020-01-29 Accept Date Merocele after 1st and 2nd weeks of operation but this difference disappeared after 4<sup>th</sup> and 8<sup>th</sup> weeks in all items. There was a statistical significance reduction in pain score and bleeding score in CMC at all times. There was no statistical significance correlation between age and pain, bleeding or synechia score in either CMC side versus Merocel nasal side. Conclusion: CMC can be a safe candidate for replacing conventional packing materials after endoscopic sinus surgery (ESS). Keywords: Carboxymethyl Cellulose, Vinyl Gloved Merocel, Chronic Rhinosinusitis

#### **INTRODUCTION**

Nasal packing is commonly used to control bleeding following operative procedures to the nose including FESS, septoplasty and conchotomy. It is also used to prevent middle turbinate lateralization, synechiae formation and restenosis after FESS [1]. However, nasal packing has some inherent disadvantages such as causing pain, bleeding and contributing to nasal mucosal damage, septal perforation, allergic reaction, sleep respiratory disturbance and decreased arterial oxygen saturation during sleep [2]. Conventional packing products such as Vaseline gauze strip and expandable polyvinyl acetate are non-absorbable materials. Many biodegradable or absorbable materials have been developed to remedy these shortcomings of conventional packing materials such as carboxy methylcellulose (CMC) which is an important industrial polymer due to its high viscosity, non-toxic, non-allergenic,

biodegradability as well as production at lower cost. However, the effects of this packing agent on mucosal healing and postoperative bleeding have not been conclusively determined [3]. The types of CMC-packing (gel or net) are dissolving completely after device hydration, capable of absorbing up to 16 times its weight. Adsorbed CMC promoted the formation of a water-rich microfibrillar gel on the fibre surfaces through the spreading out of microfibrils, leading to a decrease in friction at the fibre-fibre contact points and to the increased dispersion of fibers [4]. The removal of nasal packings has been described as the most painful part of the whole treatment. Modern nasal packings consist of resorbable materials which make their removal unnecessary, thus giving the patient more comfort [5]. Carboxymethylcellulose (CMC) is vegetable-based polysaccharide foam that actively promotes platelet aggregation upon blood contact. This non-resorbable material is

washed out in steps via repeated saline irrigations by the patients themselves, which is a commonly recommended part of the postoperative treatment [6]. After ESS most otorhinolaryngologists use endoscopy to gauge surgical success, clinical outcomes and determine patient response to adjuvant medical therapy. Endoscopy may also predict the need for revision surgery [7]. The aim of the study was to compare the outcome of dissolvable carboxy-methylcellulose (CMC) and vinyl gloved Merocele packing in functional endoscopic sinus surgery (FESS) in adult patients.

### **METHODS**

This prospective, randomized controlled trial study included 26 consecutive adult patients with a diagnosis of CRS with or without polyposis undergoing bilateral FESS, who presented to the Outpatients Clinic of the Otorhinolaryngology Head and Neck Departments, Faculty of Medicine, Zagazig University Hospital for duration from December 2017 to December 2018.

Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans

#### Inclusion criteria

Patients aged  $\geq$  18 years with bilateral CRS with or without nasal polyposis were included in the study. **Exclusion criteria** 

Patients with a previous history of ESS, patients with unilateral sinusitis Patients unfit for surgery, such as: (Patient's uncontrolled hypertension or diabetes mellitus), patients with hemoglobin concentration below 10 gm/dL, bleeding diathesis, systemic disease and pregnant women were excluded from the study.

#### **Preoperative Assessment**

Full history taking from all patients, Full radiological examination including preoperative CT scored using the Lund-Mackay radiologic grading system (0–12 for each side).

Preoperative clinical and endoscopic evaluation scores (Lund-Kennedy {LK}) were obtained for the presence of polyps (0=none, 1=confined to middle meatus, 2=beyond the middle meatus), edema (0=absent, 1=mild, 2=severe) and discharge (0=none, 1=clear and thin, 2=thick and purulent).

Oral antibiotics and methyl prednisolone were administered to patients for 1 to 2 weeks preoperatively according to the advice of the task force on rhinosinusitis.

**Surgery: General** anesthesia was performed for the procedure. Both nasal cavities were packed with cottonoids soaked in 1:10,000 adrenalinesaline solutions for 5 minutes followed by infiltration with 2% lignocaine and 1:1.00.000 adrenaline. Surgery was performed as needed the Messer linger technique. based on Intraoperative hemostasis was secured with topical vasoconstrictor and bipolar cautery. After completing the surgery and achieving complete hemostasis, the patient was observed for 5 minutes for further bleeding, then the middle meatus of one side was packed with dissolvable CMC as net form and the other side was packed with non-absorbable vinyl gloved merocel packing, which was fenestrated and inflated with 6-10ml normal saline. The packing was inserted randomized (right or left) in lateral nasal wall corresponding to middle meatus. We evaluated the efficacy of the CMC by means of degrees of bleeding, adhesion, infec-tion, and symptoms about pain and nasal obstruction.

### **Postoperative in Hospital Care**

Pulse and blood pressure were carefully monitored. Observe for epistaxis, headaches, orbital swelling, diplopia, reduced visual acuity and clear rhinorrhoea depending on the protocol of Zagazig University Hospital. Patients underwent removal of packing at 2 or 3 days after surgery. At that time, Merocel was removed entirely and CMC packing is washed out in steps via repeated saline irrigation by the patients themselves, which is a commonly recommended part of postoperative treatment.

#### **Postoperative Ambulatory Care**

Antibiotics were prescribed. Instruct patient not to blow the nose hard for at least 48 hours and only gently thereafter.Patients were scheduled to revisit the clin¬ic at 1st, 2nd, 4th, and 8th week postoperatively. During these vis¬its, the same subjective scoring criteria were evaluated and pa¬tients were examined endoscopically in each visit and asked about possi¬ble adverse reactions.

Commence topical decongestants for 5 days and a saline spray or douche for 6 weeks. Check intraoperative pus swab results if a specific organism has been isolated, prescribe appropriate antibiotics, suction-toilet the nose and check for septal hematoma or infection. Recommence longterm nasal steroids after 1 week with nasal polyposis. Decrust the nose with a rigid endoscope in the clinic if necessary

# Assessment of subjective and Endoscopic Outcome

The primary outcomes of this study were defined as a difference between the efficacy of hemostasis of CMC and that of Merocel at 2–3 days after surgery. Nasal bleeding was scored on the scale of 0 to 2 where 0 = no bleeding, 1 = spotting of gauze/traces of clotted blood in the vestibule, and 2 = continuous bleeding (anterior or postnasal bleed), Pain at removal will be recorded on a global scale, from 0 to 10 (0 = no pain and 10 = most severe pain imaginable) using a visual analogue scale (VAS) until the 8th week. The improvement in the healing postoperatively was evaluated due to Lund-Kennedy endoscopic scores at 1, 2, 4, and 8 weeks after surgery. Endoscopic findings of synechiae (between middle turbinate and lateral wall), edema, mucopurulent discharge, granulations, crusting, and stenosis were noted and the Lund-Kennedy endoscopy scoring system was used for postoperative assessment.

#### STATISTICAL ANALYSIS

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS), version 22, for Windows (SPSS Inc., Chicago, Illinois, USA). So the study descriptive statistics were presented in frequency, percentage, and mean with standard deviation. Continuous data

#### RESULTS

The age of the studied group ranged from 18 to 55 years with mean 33.7 years. Regarding sex 53.8% were male (Table 1). All studied group had nasal obstruction, 69.2% had headache and 30.8% had facial pain. Regarding comorbidity 76.9% of the studied group had other diseases (i.e., asthma and diabetes mellitus) most frequent allergic rhinitis (46.2%) (Table 2) . 23.1% of the studied group had congested ear drum and 30.8% had biodegradable nasopore (BNP) and 30.8% had post nasal discharge while 38.5% had both. Finally, 15.4% had congested throat (Table 3). 69.2% of the studied group had total maxillary opacification in both left and right side. In anterior ethmoid 76.9%

#### **Tables and figures**

**Table 1.** Demographic data of the studied group:

had total opacification in left side and 84.6% had in right side. 61.5% had total opacification in both left and right side in posterior ethmoid. 38.5% had total opacification in left side and 76.9% had in right side also 38.5% had total sphenoid opacification in left side and 53.8% had in right side. Finally, 84.6% had obstructed ostiomeatal complex (OMC) in left side and 92.3% had in right side (Table 4). All studied group had nasal obstruction. On the other hand, there were 69.2% of patients had headache, 30.8% had facial pain, 74.6% had rhinorrhea, 61.5% had hyposomia and 69.2% had post nasal discharge (Table 5). 38.5% of the studied group had polyp beyond middle meatus in left and 46.2% in right side. Regarding discharge 53.8% had mucopurulant in left side and 46.2% had in right side. Finally, there were 15.4% of the studied group had sever edema in left side and 15.4% in right side (Table 6). There were statistical significance difference between CMC and Merocele packing after 1st and 2nd weeks of operation but this difference disappeared after 4th and 8th weeks. (Table 7). There was statistical significance reduction in pain score in CMC at observed periods (Table 8). There was statistical significance reduction in bleeding score in CMC at observed periods (Table 9). There was statistical significance increase in synechiae score in Merocel group at 1st and 2nd week postoperatively (Table 10).There was no statistical significance correlation between age and pain, bleeding or synechiae score in either CMC or Merocel (Table 11).

Variable	(n=26)			
Age : (year)				
Mean ± SD	$33.7 \pm 13.9$			
Range	18 - 55			
Variable	No %			
Gender				
Male	14	53.8		
Female	12	46.2		

Sd: Standard deviation

Table 2. Clinical data of the studied group:

Variable	(n=26)		
	No	%	
Present complain:			
Nasal obstruction	26	100	
Headache	18	69.2	
Facial Pain	8	30.8	
Diagnosis			
CRS	8	30.8	
CRS+BNP	18	69.2	

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Variable	( <b>n=26</b> )			(n=26)	
	No	%			
Past History					
Asthma	6	23.1			
DM	2	7.7			
AR	12	46.2			

**CRS**: Chronic rhinosinusitis

**Table 3.** ENT Examination findings among the studied group:

Variable	(n=26)		
	No	%	
Ear:			
NAD	20	76.9	
Congested drum	6	23.1	
Nose:			
BNP	8	30.8	
BNP with post nasal discharge	10	38.5	
Post nasal discharge	8	30.8	
Threat:			
NAD	22	84.6	
Mild congested	4	15.4	

**Table 4.** Radiological Score CT scan (Lund mackay) among the studied group:

Variable	LT		RT	
	( <b>n=26</b> )		( <b>n=26</b> )	
	No	%	No	%
Maxillary sinus:				
No	0	0	0	0
Partial	8	30.8	8	30.8
Total	18	69.2	18	69.2
Ant Ethmoid:				
No	0	0	0	0
Partial	6	23.1	4	15.4
Total	20	76.9	22	84.6
Post Ethmoid:				
No	0	0	0	0
Partial	10	38.5	10	38.5
Total	16	61.5	16	61.5
Frontal				
No	0	0	0	0
Partial	16	61.5	6	23.1
Total	10	38.5	20	76.9
Sphenoid				
No	6	23.1	6	23.1
Partial	10	38.5	6	23.1
Total	10	38.5	14	53.8
OMC				
Not	4	15.4	2	7.7
Obstructed	22	84.6	24	92.3

**OMX**: ostiomeatal complex

**Table 5.** Symptoms of CRS among the studied group:

Variable		( <b>n=26</b> )		
	No	%		
Nasal obstruction:				
+ve	26	100		
Headache:				

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Variable	( <b>n=26</b> )		
	No	%	
-ve	8	30.8	
+ve	18	69.2	
Facial pain			
-ve	18	69.2	
+ve	8	30.8	
Rhinorrhea			
-ve	4	15.4	
+ve	22	74.6	
Hyposomia			
-ve	10	38.5	
+ve	16	61.5	
Post nasal discharge			
ve	8	30.8	
+ve	18	69.2	

**Table 6.** Endoscopic Score (Lund-Kennedy score) among the studied group pre- operative:

Variable	LT		RT		
	( <b>n=26</b> )		(n=26)		
	No	%	No	%	
Polyp					
None	8	30.8	8	30.8	
Confined	8	30.8	6	23.1	
Beyond middle meatus	10	38.5	12	46.2	
Discharge					
None	4	15.4	0	0	
Cleans	8	30.8	14	53.8	
Muco-purulant	14	53.8	12	46.2	
Edema scoring					
None	10	38.5	8	30.8	
Mild	12	46.2	14	53.8	
Sever	4	15.4	4	15.4	

#### DISCUSSION

Functional endoscopic sinus surgery (FESS) is the treatment of choice for CRS refractory to medical therapy. FESS is a minimally invasive, mucosal sparing surgical technique utilized to treat medically refractory CRS with or without polyps or recurrent acute rhinosinusitis. Nasal packing remains the most common procedure to prevent synechia formation and postoperative bleeding. Recently, absorbable biomaterials have become available for intranasal packing. Absorbable biomaterials are commonly used after FESS, both for hemostatic and wound-healing considerations [8]. The current study is randomized controlled trial study by cross - over design which was employed comparing the outcome of CMC versus vinyl gloved Merocel packing in both sides in the same patient after bilateral FESS for CRS regarding nasal pain, bleeding and mucosal healing at 1st, 2nd, 4th and 8th weeks, between the two packing sides.In our study, male gender was

dominant i.e. 53.8% which is comparable with the study of Nikakhlagh et al. [9]. The present study presented the symptoms in CRS patients. The commonest symptom was nasal obstruction presented in all patients followed by headache (69.2%) and fascial pain (30.8%). In diagnosis 69.2% were CRS+BNP. This finding is similar to what was reported in the study of Lourijsen et al. [10].Regarding comorbidity 76.9% of the studied group had other diseases (i.e., asthma (23.1%) and diabetes mellitus (7.7%)) most frequent AR (46.2%). There has been found association of CRS with asthma in the study of DeConde et al. [11]. Similarly, 23.1% of patients in our study had previous history of asthma. Symptoms of all patients were assessed and graded preoperatively. In the present study, 23.1% of patients had congested ear and 30.8% had BNP and 30.8% had post nasal discharge, while 38.5% of them had both (BNP with post nasal discharge). Finally, there were 15.4% of patients had

congested throat. These findings were in accordance with the study of Cain and Lal [12].69.2% of the studied group had total maxillary opacification in both left and right side. In anterior ethmoid 76.9% had total opacification in left side and 84.6% had in right side. 61.5% had total opacification in both left and right side in posterior ethmoid.On analysis of the CT scan scores in patients before surgery, there were (69.2%) patients had total maxillary opacification in both left and right side. In anterior ethmoid 76.9% had total opacification in left side and 84.6% had in right side. 61.5% had total opacification in both left and right side in posterior ethmoid. However, posterior ethmoid sinus in( 61.5%) of patients had total opacification in both left and right side. In frontal 38.5% had total opacification in left side and 76.9% had in right side also 38.5% had total sphenoid opacification in left side and 53.8% had in right side. Also, (38.5%) of patients had total sphenoid opacification in left side and( 53.8%) of them had in right side. Finally (84.6%) of patients had obstructed ostiomeatal complex (OMC) in left side and (92.3%) in right side. This finding is corroborated by the study of Sogebi et al. [13] in a similar study. The present study showed that 38.5% of the studied group had polyp beyond middle meatus in left side and 53.8% in right side, 53.8% had mucopurulant in left side and 46.2% in right side, while 15.4% of the studied group had sever edema in left side and also 15.4% in right side

In the current study, all recruited patients were able to participate in the study, and none had to be excluded. A complete data set was obtained for all participants. An identical surgical procedure was performed on both sides in all cases based on our nomenclature. After ESS, nasal packing such as CMC-packing in right or left nasal side and Merocel-packing in the other side is usually placed after the surgery to support wound healing and prevent adhesions. The present study showed that synechiae presented in 2 patients (7.8%) of CMC group at the 1st week and disappeared between the 2nd and 8th week; but it presented in 5 patients (19.2%) at the 2nd week and 2 patients (7.8%) at the 4th week. In Merocel group there was 8 patients (30.8%) presented at the 1st week. This finding is corroborated by the study of Mehan et al [14].

The crusting presented in 2 patients (7.8%) of the CMC group at the 1st week, and disappeared between the 2nd and 8th week. While, in Merocel group there was 2 patients (7.8%) presented at the 1st week and disappeared between the 2nd and 8th week. This finding is corroborated by Verim et al. [15]. The current study showed that there was a high significant differences in the effect of nasal packing on wound healing between the CMC-packed side and Merocel-packed side after 1st and

2nd weeks of operation but this difference was disappear after 4th and 8th weeks in all items with respect to the outcome measure of wound healing. This finding is corroborated by the study of Kastl et al. [16].In our study, patients had less pain and less bleeding at the 1st week post operatively and there was no adhesions at 2nd week after surgery on the CMC side. There was no significant infection or reports about severe adverse reactions. Which in agreement with the study of Cho et al. [17] who found that pain and bleeding were both markedly reduced in the absorbable group compared with the non-absorbable group. In the current study, there was statistical significance increase in synechiae score in Merocel group at 1st and 2nd week postoperative due to its removable traumatic effects, while in CMC group synechiae disappeared at the 2nd week; because CMC has good ant adhesive effect and safe material which decrease the incidence of adhesion and preserving the anatomy of nasal cavity, which in agreement with the study of Kastl et al. [16]. The current study showed that, no statistical significance correlation was found between age and pain, bleeding or synechiae score in either CMC or Merocel. These findings are corroborated by Kang et al. [8], who concluded that, a newly developed packing material, composed of a mixture of collagen, hvaluronic acid (MeroGel), and CMC (Guardcel) appears to reduce pain and shorten the hemostasis time 2–3 days after ESS.Limitations of the Study: This study was carried on small number of patients. A larger group of patients should be studied for a longer period of time to confirm the effects observed in.

#### CONCLUSION

CMC could be a safe candidate for replacing conventional packing materials after endoscopic sinus surgery (ESS).

#### Conflict of Interest: None.

Financial Disclosures: None.

Supplementary materials: The following are available online at Table S1, Table S2, Table S3 and Table S4.

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