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	A COMPARATIVE STUDY ON THE VARIOUS METHODS OF CRANIOPLASTY
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ABSTRACT Introduction Cranioplasty is a reconstructive operation to restore the large defects in the skull. In addition to cosmesis. Cranioplasty provides support, protects vital structures, and restores normal cerebrospinal fluid (CSF) flow dynamics. The ideal cranioplasty material is nonmagnetic, radiolucent, light, sterilizable, and easily affixed to the skull. The types of cranioplasty materials discussed in this study include autologous bone, bone cement- polymethylmethacrylate and titanium mesh. Unfortunately, like for decompressive craniectomies, very few prospective studies are available about cranial reconstruction. Cranioplasty can be performed by using autologous bone or heterologous materials. Autologous bone graft is often preferred to allograft devices because of its biological characteristics, the optimal matching to the bony defect, and the low cost. There is not a single material which has all the characteristics of biocompatibility, hardness, and lack of interference with radiological and neurophysiological investigations. A direct comparision of autologous bone graft, bone cement and titanium mesh cranioplasty is very difficult because the indications between series is different and there have been no prospective randomized controlled trials with long-term follow-up. Hence in this study we have tried to analyze the characteristics of various cranioplasty materials, their indications, duration to cranioplasty and results to identify the best material for cranioplasty in our institution. Materials and methods After obtaining institutional ethical committee approval, this study was conducted on patients with cranial defects who	

Materials and methods After obtaining institutional ethical committee approval, this study was conducted on patients with cranial defects who underwent surgery immediately or thereafter within a period of 1 week at Institute of Neurosurgery, GGH&MMC, Chennai. All the patients who underwent cranioplasty from October 2012 to September 2014 were included in the study. The patient details were collected and the Institute of Neuro Surgery. These patients were analyzed to ascertain the best material for cranioplasty, complications due to the procedure and the outcome of the procedure.

Results- The incidence of superficial infections has been shown in our study to be the highest in the autologous bone graft group and this has been found to be statistically significant and has been proven in others studies as well. Osteomyelitis was found to be exclusive to the autologous bone graft group. There is an increase incidence in seroma formation in the bone cement group. Residual defect post cranioplasty was also exclusive to the autologous bone graft group. In our study hematoma formation was higher in the PMMC group.Seizures as a complication of cranioplasty occurred in all there materials used for cranioplasty and there was no statistical significance in the incidence of seizures amongst the three materials studied. Titanium mesh by far in the study has proved to be superior material for cranioplasty with regard to wound infection and seroma formation in our institution.

KEYWORDS : Cranioplasty, bone defect, PMMC, titanium mesh, wound infection.

INTRODUCTION

Cranioplasty is a reconstructive operation to restore the large defects in the skull. In addition to cosmesis, cranioplasty provides support, protects vital structures, and restores normal cerebrospinal fluid (CSF) flow dynamics. Throughout history, a range of cranioplasty materials have been used, including animal bone and metals. The ideal cranioplasty material is nonmagnetic, radiolucent, light, sterilizable, and easily affixed to the skull. The types of cranioplasty materials discussed in this study include autologous bone, bone cementpolymethylmethacrylate and titanium mesh. Unfortunately, like for decompressive craniectomies, very few prospective studies are available about cranial reconstruction. This procedure is always a second step performed after a previous surgical procedure where autologous bone has been removed. Cranioplasty can be performed by using autologous bone or heterologous materials. Very few adverse events have been connected directly to the materials used in cranioplasty. Autologous bone graft is often preferred to allograft devices because of its biological characteristics, the optimal matching to the bony defect, and the low cost. There is very little agreement on the best material for heterologous cranioplasty. There is not a single material which has all the characteristics of biocompatibility, hardness, and lack of interference with radiological and neurophysiological investigations. A direct comparision of autologous bone graft, bone cement and titanium mesh cranioplasty is very difficult because the indications between series is different and there have been no prospective randomized controlled trials with long-term follow-up. Hence in this study we have tried to retrospectively analyze the characteristics of various cranioplasty materials, their indications, duration to cranioplasty and results to identify the best material for cranioplasty in our institution.

AIM OF THE STUDY

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The aim of this study is to compare the various methods of cranioplasty ie, autologous bone graft, polymethylmethacrylate bone cement and titanium mesh cranioplasty done at our institute and to study the complications associated with the above materials used and also to identify the best material to use for cranioplasty.

MATERIALS AND METHODS

After obtaining institutional ethical committee approval, this study was conducted on patients with cranial defects who underwent surgery immediately or thereafter within a period of 1 week at Institute of Neurosurgery, GGH&MMC, Chennai. All the patients who underwent cranioplasty from October 2012 to September 2014 were included in the study. Patients whose age wass less than 18 years and patients with sepsis, collagen vascular disease, diabetes mellitus, rheumatic heart diseases and infective endocarditis were excluded from the study. The patient details were collected and the Institute of Neuro Surgery. These patients were analyzed to ascertain the best material for cranioplasty, complications due to the procedure and the outcome of the procedure. Statistical analysis was done using SPSS software to assess the multifactorial causes of complications and outcomes.

DISCUSSION

In our study we set out to compare the treatment outcomes and complication profiles of the three commonly used materials in cranioplasty in our institution, that is autologous bone graft, polymethylmethacrylate and titanium mesh. In the study that we conducted we studied the incidence of seizures in the cranioplasty population and found that the 8.7% of the patients who underwent cranioplasty, 21% of patients who underwent cranioplasty with bone cement and 7.9% of patients who underwent Titanium mesh. This when compared to the study done by Zanaty et al in a retrospective study with 348 patients found that (Zanaty et al., 2015) seizures occurred in 14.37% of their study population who underwent cranioplasty and the same was 14.8% in another study by Lee et al(H. J. Lee, Choi, & Chung, 2014). All the studies mentioned have shown no difference between the three materials studied by way of seizure incidence. Amongst the study population 8.7% of autologous bone grafts, 21.1% of the bone cement cranioplasty and 7.9% of Titanium mesh cranioplasty patients developed seizures. This in comparison with a study in England by Coulter et al (Coulter et al., 2014) which was 8.4% with titanium mesh only. There were no other studies that compared different materials used in cranioplasty with regard to seizures. Hence this turns out to be the highlight of this study. Though

there is an apparently higher incidence of seizures with bone cement this was found to be statistically insignificant by using the Pearson Chi-Square test. This might mean that there is a room for type II error, where in there might actually be a significant difference. In the study we performed there were no cases of superficial infections in the titanium group which in the autologous bone graft and bone cement groups were 26% and 31%. This was found to be statistically significant. In the study by Zanaty et al 14.9% of the patients developed superficial infection. While it was 6.6% in the study by Wachter et al(Wachter, Reineke, Behm, & Rohde, 2013). In the latter two studies this superficial infection rate is irrespective of the material used for cranioplasty. In our study the autologous bone graft have been found to have lesser infection rates compared to bone cement which is a variation from the study by Matsuoto et al which shows higher incidence in autologous bone graft(Matsuno et al., 2006). With regard to deep infection deep infection was found in 66.7% of autologous bone graft, 33.3% of bone cement and none of the titanium cranioplasty cases. This when compared to the retrospective study done by Zatany et al showed a 11.4% occurrence of deep post cranioplasty infection. In another study by Bobinski et al that compared polymethylmethacrylate with autologous bone graft (Bobinski, Koskinen, & Lindvall, 2013) it was found that the overall infection rates between the two groups was not statistically significant. Hence we may conclude that though there might be a statistical difference between the Titanium mesh and the other two methods taken collectively, its possible that there may not be any difference in infection rates over all between the bone graft and polymethyl metacrylate cranioplasties. This is in contradiction of the study results of Lethaus et al that showed superior results with artificial implants over autologous bone (Lethaus, Bloebaum, Koper, Poort-Ter Laak, & Kessler, 2014) .With regard to the post-procedure hematoma formation in our study, there were one case each in the Bone cement group and the titanium mesh group. With an overall percentage of 7.9% of the patients studied. This was found to be insignificant at a pvalue of 0.552, meaning that there was no significant difference in the rate of hematoma formation within the three groups. In the study by Zanaty et al the total rate of hematoma formation was 6.9% which is slightly lesser than the numbers in our study. In comparison with the studies by Broughton et all and Lee et al there is a seemingly significant variation in the hematoma formation rates between 5.7% and 1.65% respectively (Broughton, Pobereskin, & Whitfield, 2014) (E. I. Lee et al., 2014). In the studies that compared different materials used with regard to hematoma formation, the study by Bobinski et al found a statistically significant increased incidence of hematoma formation amongst the autologous bone graft group when compare to the bone cement group. So it is possible that there might be a Type II statistical error in our study result with regard to post-operative hematoma formation. With regard to seroma formation, the highest incidence of seroma formation was noted in the bone cement group in our study which was significantly higher than in in the bone cement group compared to the autologous bone graft and the titanium mesh groups with a p-value of 0.025. This is in contradiction to the study by Huang.J et al that says that polymethylmetacrylate has no complications with regard to seroma formation, as a material for cranioplasty(Huang et al., 2015). So we may infer that this aspect of seroma formation may be because of the chemical content present in the form of polymethylmethacrylate and the inert nature of the titanium mesh which does not cause any reaction to tissues. Moving on to the discussion on Wound dehiscence, 8.7% of the patient in the autologous bone graft group developed wound dehiscence, in contrast to the 5.3% of the patients in the bone cement group and none of the patients in the patients who underwent titanium mesh cranioplasty. Statistically this does not seem to be significant with a p-value of 0.206

but it correlates well with the fact that 26.1% or the patients with autologous bone grafts also had residual skull defects which is most likely to be the cause of CSF leak. Wound dehiscence is another aspect which showed no statistical significance between the autologous bone graft group and the bone cement group each of which ad 8.7% and 5.3% wound dehiscence rates respectively. This was not observed in the titanium mesh group. These numbers correlate exactly with the CSF leak rates that occurred in the study groups. Hence the wound dehiscence was a consequence of CSF leak which in turn is an offshoot of the residual bone defect which is inevitable in the autologous bone graft patients due to technical reasons and the nature and site of decompressive craniectomy. The incidence of osteomyelitis was noticed only in the autologous bone graft group and is an expected complication as the autologous bone graft used is for all practical purpose a graft and not a flap with a pedicle supply. Hence it is intuitive that osteomyelitis would occur in only the Autologous bone graft

group. Osteomyelitis in the autologous bone graft group might be because of the handling of bone material and also placing it in a neo pouch in the abdominal cavity which may favor the translocation of microbes and colonization leading to infection.

RESULTS AND CONCLUSION

In our study we set out to compare the treatment outcomes and complication profiles of the three commonly used materials in cranioplasty in our institution, that is autologous bone graft, polymethylmethacrylate and titanium mesh. In the study that we conducted we studied the incidence of seizures in the cranioplasty population and found that the 8.7% of the patients who underwent cranioplasty, 21% of patients who underwent cranioplasty with bone cement and 7.9% of patients who underwent Titanium mesh. This when compared to the study done by Zanaty et al in a retrospective study with 348 patients found that (Zanaty et al., 2015) seizures occurred in 14.37% of their study population who underwent cranioplasty and the same was 14.8% in another study by Lee et al(H. J. Lee, Choi, & Chung, 2014). All the studies mentioned have shown no difference between the three materials studied by way of seizure incidence. Amongst the study population 8.7% of autologous bone grafts, 21.1% of the bone cement cranioplasty and 7.9% of Titanium mesh cranioplasty patients developed seizures. This in comparison with a study in England by Coulter et al (Coulter et al., 2014) which was 8.4% with titanium mesh only. There were no other studies that compared different materials used in cranioplasty with regard to seizures. Hence this turns out to be the highlight of this study. Though there is an apparently higher incidence of seizures with bone cement this was found to be statistically insignificant by using the Pearson Chi-Square test. This might mean that there is a room for type II error, where in there might actually be a significant difference. In the study we performed there were no cases of superficial infections in the titanium group which in the autologous bone graft and bone cement groups were 26% and 31%. This was found to be statistically significant. In the study by Zanaty et al 14.9% of the patients developed superficial infection. While it was 6.6% in the study by Wachter et al(Wachter, Reineke, Behm, & Rohde, 2013). In the latter two studies this superficial infection rate is irrespective of the material used for cranioplasty. In our study the autologous bone graft have been found to have lesser infection rates compared to bone cement which is a variation from the study by Matsuoto et al which shows higher incidence in autologous bone graft(Matsuno et al., 2006). With regard to deep infection deep infection was found in 66.7% of autologous bone graft, 33.3% of bone cement and none of the titanium cranioplasty cases. This when compared to the retrospective study done by Zatany et al showed a 11.4% occurrence of deep post cranioplasty infection. In another study by Bobinski et al that compared polymethylmethacrylate with autologous bone graft (Bobinski, Koskinen, & Lindvall, 2013) it was found that the overall infection rates between the two groups was not statistically significant. Hence we may conclude that though there might be a statistical difference between the Titanium mesh and the other two methods taken collectively, its possible that there may not be any difference in infection rates over all between the bone graft and polymethyl metacrylate cranioplasties. This is in contradiction of the study results of Lethaus et al that showed superior results with artificial implants over autologous bone (Lethaus, Bloebaum, Koper, Poort-Ter Laak, & Kessler, 2014) .With regard to the post-procedure hematoma formation in our study, there were one case each in the Bone cement group and the titanium mesh group. With an overall percentage of 7.9% of the patients studied. This was found to be insignificant at a pvalue of 0.552, meaning that there was no significant difference in the rate of hematoma formation within the three groups. In the study by Zanaty et al the total rate of hematoma formation was 6.9% which is slightly lesser than the numbers in our study. In comparison with the studies by Broughton et all and Lee et al there is a seemingly significant variation in the hematoma formation rates between 5.7% and 1.65% respectively (Broughton, Pobereskin, & Whitfield, 2014) (E. I. Lee et al., 2014). In the studies that compared different materials used with regard to hematoma formation, the study by Bobinski et al found a statistically significant increased incidence of hematoma formation amongst the autologous bone graft group when compare to the bone cement group. So it is possible that there might be a Type II statistical error in our study result with regard to post-operative hematoma formation. With regard to seroma formation, the highest incidence of seroma formation was noted in the bone cement group in our study which was significantly higher than in in the bone cement group compared to the autologous bone graft and the titanium mesh groups with a p-value of 0.025. This is in contradiction to the study by Huang.J

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RESULTS AND CONCLUSION

The incidence of superficial infections has been shown in our study to be the highest in the autologous bone graft group and this has been found to be statistically significant. The same has been proven in others studies as well. Though there might be room for Type I error because of the relatively smaller study population, the results have been in conjuncture with the other larger studies and hence the chances of type I error need not be entertained. Osteomyelitis was found to be exclusive to the autologous bone graft group and was statistically nearly significant. With regard to seroma formation there is an increase incidence in seroma formation in the bone cement group which is statistically significant. Residual defect post cranioplasty was also exclusive to the autologous bone graft group due to technical considerations of the prior decompressive procedures bearing on the defect left and the size of autologous bone graft that is available. In our study hematoma formation was higher in the PMMC group and this was found to be insignificant. This result which is in contrast to other larger studies and hence we entertain a possibility of type II error and hence may need further research. Seizures as a complication of cranioplasty occurred in all there materials used for cranioplasty and there was no statistical significance in the incidence of seizures amongst the three materials studied. This has also been proved by other studies as discussed above. CSF leak is a technical complication and was not statistically significant. Wound dehiscence is a consequence of CSF leak and exclusively occurred in patients who had CSF leak only. Hence titanium mesh by far in the study has proved to be superior material for cranioplasty with regard to wound infection and seroma formation in our institution.

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