A RANDOMISED CONTROLLED TRIAL- COMPARING CEMENTED MODULAR BIPOLAR HEMIARTHROPLASTY WITH CEMENTED TOTAL HIP REPLACEMENT IN FRACTURES OF FEMORAL NECK IN ELDERLY PATIENTS

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ABSTRACT

BACKGROUND

Femoral neck fractures have remained as 'unsolved fractures' till today due to the high rate of associated complications. In the Indian scenario, the focus is always on femoral head preservation. In the elderly, however, the options in managing femoral neck fractures seem to be more in favour of head sacrificing surgery such as arthroplasty and the procedure may vary from either cemented to uncemented fixation or hemiarthroplasty to total joint replacement. Nevertheless, the 'gold standard' and the most appropriate treatment for these fractures remain controversial.

The purpose of this study was to analyse the outcome of displaced femoral neck fractures in elderly patients who were fit to receive either a hemiarthroplasty using cemented modular (bimodular/bimod) bipolar prosthesis or total hip arthroplasty using a cemented prosthesis in terms of operation time, blood loss and transfusion, duration and cost of hospitalisation, hip joint function, pain relief, post-operative complications, rate of dislocation, revision and mortality.

MATERIALS AND METHODS

Over a period of 3 years (2013 - 2016), a prospective randomised controlled trial study was carried out for a total of 40 cases of acute fracture of neck of femur in elderly patients, aged more than 65 yrs. attending the OPD and Emergency Department of Orthopaedics, Gauhati Medical College and Hospital. The patients were followed up and were evaluated clinically, radiologically and functionally (using Harris Hip Score).

RESULTS

In the HRA group, we achieved excellent functional results in 70% cases and in the THA group we achieved excellent functional results in 90% cases and there was no statistically significant difference in terms of Harris Hip Score in both the groups.

CONCLUSION

From our study, we have seen that there is no significant difference in treatment of neck of femur fractures treated with THA and HRA in terms of functional results and intra- and post-operative complication. However, there is a significant difference in intra-operative blood loss between the two types of procedures.

KEYWORDS

Fracture Neck of Femur, Elderly, Displaced, Cemented Modular Hemiarthroplasty vs Cemented Total Hip Arthroplasty, Randomised Controlled Trial.

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BACKGROUND

Femoral neck fractures have remained as 'unsolved fractures'^{1,2} till today due to the high rate of associated

complications, which include non-union and avascular necrosis of the femoral head even after use of best method of fixation devices.

It is a common skeletal injury occurring with trivial trauma in the osteoporotic bone of elderly patients, especially in females. The management started with closed reduction and immobilisation in POP hip spica in the early part of 20th century.³ High incidence of non-union, bed sores and respiratory complications led to condemnation of plaster and exploration of other methods like closed reduction and internal fixation. The initial fixation devices failed to produce compression at fracture site and also could not neutralise the rotatory forces and shearing strain at the fracture site.

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Advent of CT scan explained the fracture geometry regarding posterior comminution and loss of position during time of fixation. The use of three partially threaded cancellous screws is probably the best available method of fixation till date. The presentation at different ages poses different problems related to the management, the burning issues being fixation failure in osteopenic bone of the elderly, marked displacement of fragments with posterior comminution, disruption of blood supply and a higher incidence of avascular necrosis (AVN).³

Whether fractures of the femoral neck in elderly patients are treated with internal fixation, hemiarthroplasty or total hip replacement (THR), should be determined by the degree of fracture displacement, the patient's age, functional demands and risk profile, such as level of cognitive function and degree of physical fitness.^{4,5} However, the surgical treatment of displaced femoral neck fractures differs from the treatment of many other hip fractures because the available treatment modalities, internal fixation (IF), hemiarthroplasty (HA) and total hip replacement (THR) differ in surgical impact, complications and long-term outcomes. Consequently, each modality has its own unique characteristics, advantages and disadvantages.

In the Indian scenario, the focus is always on femoral head preservation. In the elderly, however, the options in managing femoral neck fractures seem to be more in favour of head sacrificing surgery such as arthroplasty and the procedure may vary from either cemented to uncemented fixation or hemiarthroplasty to total joint replacement.³ Main reason being health of the patient would not permit a second operation and financial constraints.

The goal of treatment is to return the patient to his or her pre-morbid status of function. Nevertheless, the 'gold standard' and the most appropriate treatment for these fractures remain controversial.

Femoral neck fracture in the elderly poses a problem of poor bone quality and co-morbid medical conditions. Hagino et al evaluated the prognosis among different age groups in elderly patients aged 65 years and above treated for hip fractures.⁶ Replacement arthroplasty, either hemiarthroplasty (Austin Moore, Thompson's or Bipolar prosthesis) or total hip replacement was found to be ideally suitable for the elderly population as a primary procedure to tackle the problem of fixation failure, non-union and AVN.

There appears to be a consensus among orthopaedic surgeons that unipolar or bipolar hemiarthroplasty is the preferred treatment for displaced intracapsular fractures in elderly patients with low functional demands.⁷ THA is advocated in cases where life expectancy is significant and when acetabular disease is present. For older people, bipolar arthroplasty may be a better option. Specific indications exist for cemented and cementless replacements.³ It is almost certain that better short-term clinical and functional outcomes can be obtained from cemented femoral fixation than those from the uncemented.⁸ At least the cemented group is equal, if not superior to the uncemented group. However, for the relatively healthy, active and mentally alert elderly patient, treatment is still controversial.⁷ There is inadequate evidence to support the choice between different types of arthroplasty. There seemed to be an advantage for THR over bipolar hemiarthroplasty, especially at longer followup, but various authors recommended further trials to verify it.⁹

The purpose of this study was to analyse the outcome of displaced femoral neck fractures in elderly patients, who are fit to receive either a hemiarthroplasty using cemented modular (bimodular/bimod) bipolar prosthesis or total hip arthroplasty using a cemented prosthesis in terms of operation time, blood loss and transfusion, duration and cost of hospitalisation, hip joint function, pain relief, post-operative complications, prosthesis loosening, rate of dislocation, revision and mortality.

MATERIALS AND METHODS

Over a period of 3 years (2013 - 2016), a prospective randomised controlled trial study was carried out for a total of 40 cases of acute fracture neck of femur in elderly patients aged more than 65 yrs. attending the OPD and Emergency Department of Orthopaedics, Gauhati Medical College and Hospital who meet the inclusion and exclusion criteria. This study was cleared by the Ethical Committee of Gauhati Medical College, Guwahati. The sample size was decided as per the admission rate and by surveying the average number of acute neck of femur fracture patients within the said age group posted for replacement surgeries in the last 3 years before starting our study as documented in the operation registration books of orthopaedics operation theatre in our institute. In a pilot study the mean surgical time in HRA group, 71.3 minutes with a standard deviation of 25 minutes. To detect a difference of 25 minutes, which was a priority decided to be clinically important; 16 patients in each group is necessary to achieve a power of 80% with alpha of 5%. Thus, considering attrition rate of at least 15% a sample of 20 in each group was taken.

All patients above 65 yrs. with fresh neck fractures (< 2 weeks) and who were able to walk prior to the fracture were included in the study.

Patients aged < 65 yrs., > 80 yrs., duration of injury > 2 weeks with active infection, advanced arthritis or with a pathological fracture were excluded from the study. All the cases were followed up for a minimum period of twelve months.

Preoperatively, Buck's traction with appropriate weight was applied to the fractured lower limb with an aim of relieving pain, preventing shortening and to reduce unnecessary movements of the injured limb. On receiving the patient, initial symptomatic treatment and a detailed history of the patient was taken.

The initial radiographs included antero-posterior view of the affected hip joint of pelvis with both hips were taken for all the patients, keeping the fractured limb in 15° internal rotation to bring the neck parallel to x-ray film.

After assessment by an anaesthetist for fitness for operation, randomisation was done using the plan generated from the website www.randomization.com to allocate the patient into one of the following two treatment models-

1. Hemi replacement arthroplasty using cemented modular bipolar prosthesis (20 patients).
2. Total hip arthroplasty using cemented prosthesis (20 patients).

For all our patients, posterior approach was used. The modular femoral component (DePuy) with a 28-mm head was used in all cases with either a bipolar Hastings head or with an OGEE (DePuy/Johnson and Johnson) acetabular component. The same cementing technique was used in both groups. A distal restrictor and a proximal seal were used when cementing the femoral component and a cement

pressuriser was used when cementing the acetabular component.

Intravenous antibiotics (Ceftriaxone with Sulbactam 1.5 gm and Amikacin 500 mg) were administered twice daily for the first 3 days and then shifted to Oral Cefuroxime 500 mg twice daily for the next 7 days. Patients were taught quadriceps strengthening exercises, weight bearing with support and leg dangling by the side of the bed as soon as the pain subsides to a tolerable limit. The patients were regularly followed up at 6 weeks, 3, 6, 9, 12, 24 and 36 months and were evaluated clinically, radiologically and functionally (using Harris Hip Score). The statistical analysis was done by using unpaired 't' test for continuous numerical values and chi-square test for categorical values and the tables were analysed using GraphPad InStat 3 software.

RESULTS

1. The average age of the patients in our series was 70.0 years (SD= 3.63 years) with most patients between 65 - 70 years. Maximum age was 76 years and minimum age was 66 years with mean age of 69.58 years (SD= 3.8 years) in males and 70.62 years (SD= 3.5 years) in females.
2. The fractures were more commonly encountered on the right side (55%). There were no bilateral cases.
3. All of the patients had minimal trauma, most of them slipped and fell down on flat ground or in bathroom and were not able to walk or stand.
4. Associated disorders like Diabetes Mellitus, Hypertension, Chronic Obstructive Pulmonary Disease and Anaemia were present in about 28 cases (70%). The patients were taken up for surgery as soon as they became medically fit for the surgical procedure.
5. Most of the cases (40%) were operated in 2 - 7 days following injury. The mean time interval between surgery and trauma was 4.5 days (2 - 12 days).
6. The average operative time of surgery in both the groups combined was 81.95 (62 - 120 min) with a standard deviation of 20.49. The mean operative time of surgery in the group HRA using MODULAR prosthesis was 71.3 mins. (62 - 101 mins.) with standard deviation of 9.28 (95% confidence interval 63.23 - 79.37). The mean operative time of surgery in group using THA was 92.6 mins. (85 - 120 mins.) with standard deviation of 8.29 (95% confidence interval 85.23 - 101.97). On statistical analysis comparing the two groups, the p-value was found to be 0.67 (unpaired 't' test), which is statistically insignificant. This indicates that there is no statistically significant difference between the two groups in relation to duration of surgery.

Figure 1. Bar Diagram showing Average Operative Time in HRA and THA

7. Closed suction was used in all the cases and the amount of blood collected in the suction jar minus the amount of saline use was calculated to find the rough estimate of the amount of blood loss in each case. The average intra-operative blood loss in our study was 407.5 mL (standard deviation 90.9). The average blood loss in the HRA group was found to be 280.0 mL (standard deviation- 100.55, 95% confidence limit from 208.07 to 351.93). The average blood loss in the THA group was found to be 485.0 mL (standard deviation 229.79, 95% confidence limit from 370.63 to 699.37). The above two values were tested statistically by unpaired 't' test. The p value was < 0.0001, which is statistically significant. This indicates that there exists a statistically significant difference between the two groups in relation to intra-operative blood loss, which may affect the outcome. However, no hypovolaemic shock in the patients were encountered in our study.

Figure 2. Bar Diagram showing Average Blood Loss during Operation

8. Complications: No general complication from surgery like septicaemia, deep vein thrombosis, pulmonary emboli, CVA, etc. was encountered. There was also no reported case of dislocation in our study. No loosening of implant, late infection and mortality was recorded in our series. However, in the HRA group we had two cases of bed sore of superficial grade 1, which responded to use of pneumatic bed and dressing. The bed sore was seen in patients with prolonged immobilisation secondary to delay in surgery due to comorbidities like cachexia, diabetes or anaemia. Lefavre et al¹⁰ showed that when the surgery was delayed for more than 24 hrs., it was significantly related to increase in pressure sore. Grimes et al¹¹ showed that the risk of decubitus ulcer increased as the surgery was delayed for more than 96 hrs.

In the THA group, we had one case of superficial infection which responded to antibiotics with regular dressing. Blomfeldt et al,¹² Van den Bekerom et al¹³ in their study also reported superficial infection in either groups. The difference between the groups was not statistically significant.

Clinical Studies	Superficial Infection	
	HRA	THA
Blomfeldt et al ¹²	3.3%	3.3%
van den Bekerom et al ¹³	2.1%	1.7%
Maini PS et al ¹⁴	4.1	-
Our study	0	5%

Table 1. Percentage of Infection in Various Studies

9. Harris Hip Scoring system was used to evaluate the functional result in our study. Patients who had a normal range of motion, minimum limp, no pain and who rarely used a cane were graded as having excellent result (score 90 - 100). Patients with score 80 - 89 were graded good result. Those with score 70 - 79 were graded fair and those with score less than 70 were graded as poor.

At 12 months followup in the HRA group, 14 patients (70%) had excellent results and 6 patients (30%) had good results, whereas in the THA group 18 patients (90.0%) had excellent results and 2 patients (10.0%) had good result.

Figure 3. Bar Diagram showing Functional Results in HRA and THA Group

10. As per the Harris hip scoring system, the pain component was measured and accordingly in the HRA group 15 patients (75%) had no pain; 3 patients (15%) had slight pain and 2 patients had mild pain (10%); whereas in the THA group 18 patients (90%) had no pain and 2 patients (10%) had slight pain.
11. In the HRA group 16 patients (80%) had no limp; 4 patients (20%) had slight limp; whereas in the THA group 18 patients (90%) had no limp, 2 patients (10%) had slight limp.
12. In the HRA group 12 patients (60%) climbed the stairs without support; 8 patients (40%) climbed the stairs with support of railing; whereas in the THA group 16 patients (80.0%) climbed the stairs without support; 4 patients (20.0%) climbed the stairs with support of railing.
13. In the HRA group 14 patients were able to sit comfortably in ordinary chair for one hour; 6 patients were able to sit on high chair for 30 minutes; whereas in the THA group 16 patients (80.0%) were able to sit comfortably in ordinary chair for one hour; 4 patients (20.0%) were able to sit on high chair for 30 minutes. On gradual followup, pain, limp and climbing stairs improved in the patients.

14. Range of Movements

a) Flexion

The mean range of hip flexion in the HRA group was found to be 108 degrees, (standard deviation 11.35). The worst flexion range was found to be 90 degrees. The mean range of hip flexion in the THA group was found to be 109 degrees, (standard deviation 8.76). On statistical analysis comparing the two groups the p-value was found to be 0.254, which is statistically insignificant.

b) Abduction

The mean range of abduction in the HRA group was found to be 41.5 degrees (standard deviation 2.42), while the mean range of abduction in the THA group was also found to be 42 degrees (standard deviation 2.58). On statistical analysis comparing the two groups the p-value was found to be 0.997, which is statistically insignificant.

c) Adduction

The mean range of adduction in the HRA group was found to be 38.5 degrees, while in the THA group the mean range of adduction was 38.5 degrees. On statistical analysis comparing the two groups the p-value was found to be 1.000, which is statistically insignificant.

d) Internal Rotation

The mean range of internal rotation in the HRA group was found to be 42 degrees (standard deviation 2.58), while in the THA group the mean range of internal rotation was 42.5 degrees (standard deviation 2.63). On statistical analysis comparing the two groups the p-value was found to be 0.997, which is statistically insignificant.

e) External Rotation

The mean range of external rotation in the HRA group was found to be 39.5 degrees (standard deviation 3.69), while the mean range of external rotation in the THA group was found to be 42.0 degrees (standard deviation 2.58). On statistical analysis comparing the two groups the p-value was found to be 0.996, which is statistically insignificant.

15. The average time of partial weight bearing was 1.65 days with standard deviation of 0.81.
16. The average time of full weight bearing in the group of HRA was 1.9 days with standard deviation of 0.88, while in the group of THA 1.4 days with standard deviation of 0.69. However, on statistical analysis it was found that there was no significant difference in both the groups in terms of time for partial weight bearing (p- 0.985 with 9 degrees of freedom).
17. All cases were followed up according to pre-fixed protocol with followup of 6, 9, 12 months and subsequently at 2 and 3 yrs. The average followup was 24.4 months with a standard deviation of 2.56. The maximum followup in our study was 36 months. The average followup in the HRA group was 22 months and in THA group was 23.8 months and the difference was statistically not significant (p-0.977).

DISCUSSION

Despite the improvements in the understanding of the fracture, implant designs, surgical technique and after care, the dilemma of the right choice of treatment for the right patient remains. The marked improvements in the socioeconomic conditions and the quality of life have resulted in improvement in life expectancy, as also to a rise in the incidence of fracture neck of femur.

While our study was limited to 40 cases, Blomfeldt R et al¹² studied 120 cases, MPJ Van den Bekerom et al¹³ studied 252 cases and Lee et al¹⁵ studied 126 cases. This is due to the fact that this study was limited to a very short duration. Also, financial constraints and unawareness of this procedure to the patient limited the number of patients for this study.

The average age incidence in our study was 70.0 years with a range of 65 to 80 years. Our study was comparable to other studies as mentioned in the table.

Clinical Studies	Mean Age in Years
Blomfeldt et al ¹²	81 y (70-90)
Gupta et al ¹⁶	60 y (50-80)
Van den Bekerom et al ¹³	81.1 y (70.2-95.6)
Keating JF ⁹	75.4 y (68-82)
Our Study	70.0 y

Table 2. Age Distribution in Various Comparable Studies

In the HRA group about 16 patients (80%) got operated within 7 days of admission; 4 patients (20%) got operated between 7 - 14 days of admission; whereas in the THA group 14 patients (70%) got operated within 7 days of admission; 6 patients (30%) got operated between 7 - 14 days of admission. In neither of the groups did the surgery got delayed more than 14 days from admission.

The reason for delay was the associated morbidity with the patient like diabetes, hypertension, anaemia and COPD. For these patients, a longer period of pre-operative evaluation and optimisation was required. Novack et al¹⁷ showed the length of surgery delay had a gradual effect on increasing mortality of both short-term amid long-term. Majumdar et al¹⁸ reported no independent association between timing of surgery and mortality. Evidences in the literature regarding the effect of delay to surgery on mortality are conflicting and there is no conclusive evidence. Although, there is no solid evidence that early surgery would improve mortality, there is widespread evidence in the literature that other outcomes including morbidity, the incidence of pressure sores and the length of hospital stay could be improved by shortening the waiting time of hip fracture surgery. This probably holds good if head preserving surgery is attempted. Early surgery can bring better pain relief. Hence, it is still apt to treat these patients as soon as their bodies meet the basic anaesthetic requirements. In the HRA group, the mean duration of surgery ranged from 62 - 101 minutes (mean 71.3 mins.) with a mean amount of blood loss of 280 mL, whereas in the THA group the mean duration of surgery ranged from 85 - 120 minutes (mean 92.6 mins.) and mean amount of blood loss being 485.0 mL. Surgical time (71.3 minutes versus 92.6 minutes) and blood loss (280 mL versus 485 mL) was greater for the THA group. The difference between the groups was significant ($p < 0.0001$).

Blomfeldt R et al¹² reported duration of 78 mins with a blood loss of 320 mL in HRA group and 102 mins. with a blood loss of 460 mL in THA group. The difference between the groups were significant ($p < 0.001$). Van den Bekerom et al¹³ and Zhao Y¹⁹ in their study recorded blood loss and surgical time, which was found to be lower in case of HRA compared to THA.

Clinical Studies	Mean Amount of Blood Loss in Millilitres		Mean Duration of Surgery in Minutes	
	HRA	THA	HRA	THA
Blomfeldt R et al ¹²	320	460	78	102
Giannini et al ²⁰	380	460	71	76.7
Our Study	280	485	71.3	92.6

Table 3. Mean Blood Loss and Duration of Surgery in Various Studies

MPJ Van den Bekerom et al¹³ and Zhao Y¹⁹ in their study recorded higher dislocation rate in THA compared to HRA. Blomfeldt et al¹² did not report any dislocation in either group. In our study, there was no incidence of any dislocation. We could probably prevent this complication by using a long knee brace keeping the limb in abduction for first 48 hrs. in all our cases.

In our study, there was no statistical difference in the pain scoring (p value= 0.322) between the HRA and THA groups, which matches with the other similar studies like Van den Bekerom et al¹³ where mean HHS pain was 37.5 and 40.0 for HRA and THA respectively. But Blomfeldt et al¹² reported mean HHS pain at 12 months was 39.1 and 43.1 for HRA and THA respectively ($p < 0.001$). Macaulay et al²¹ found that THA patients had significantly less pain than hemiarthroplasty patients (54.8 ± 7.9 vs 44.7 ± 10.5 , $P = .04$). Dorr et al²² showed that no difference was found in the level of pain, ambulation or aids required between the THA group and the hemiarthroplasty group, except for active community ambulators who demonstrated decreased endurance capability when treated with hemiarthroplasty.

Clinical Study	Results of Pain	
	HRA	THA
Van den Bekerom et al ¹³	37.5	40.0
Blomfeldt et al ¹²	39.1	43.1
Our Study	38.2	40.6

Table 4. Results of Pain in Various Studies

The results in our study did not show any statistical difference in the evaluation of limp ($P = 0.088$), ability to walk ($P = 0.439$) and use of walking aids ($P = 0.270$) which matches with other similar studies like Van den Bekerom et al¹³ reported no difference in function in two groups after 12 months. Baker et al²³ reported better function in THA patients compared to HRA patients ($p = 0.039$). Blomfeldt et al¹² in their study reported mean HHS function score for HRA and THA as 31.6 and 35.3 respectively after 12 months. The results were significant ($p < 0.037$).

In our study, the HRA group mean HHS ROM was found to be 2.005 and for THA group was 1.9. In Blomfeldt et al¹² study, the mean HHS ROM for HRA and THA group was 4.7 and 4.7 respectively ($p = 0.435$).

Clinical Studies	HRA	THA
Blomfeldt et al ¹²	4.7	4.7
Our Study	2.005	1.9

Table 5. Mean Range of Movement Score in Comparable Study

Total Functional Result at 12 Months

In the HRA group, 14 patients (70%) had excellent results and 6 patients (30%) had good results, whereas in the THA group 18 patients (90.0%) had excellent results and 2 patients (10.0%) had good result. There was no statistically significant difference in the functional outcome ($p= 0.9808$) between the two groups in our study. The total functional results in terms of sitting on chair, independent walking and climbing stairs improved at 24 and 36 months followup. And our study results match most of the other similar studies mentioned below.

One year Harris Hip score results were equivalent and there were no differences in ability to walk, use of analgesics or place of living in both the groups.

Blomfeldt R et al¹² in their study found the mean Harris hip score difference in favour of the THR group at both reviews and increased with time. MPJ Van den Bekerom et al¹³ reported after one and five years followup the results of bipolar hemiarthroplasty are similar to THR for the treatment of patients aged ≥ 70 years with displaced femoral fractures. Baker et al²³ in 2006 showed superior short-term results in their comparative study in cases operated by total hip arthroplasty.

Clinical Studies	Mean Harris Hip Functional Scoring	
	HRA	THA
Blomfeldt et al ¹²	79.4	87.2
Van den Bekerom et al ¹³	73.9	76
Giannini S ²⁰	75.5	80.7
Macaulay et al ²¹	65.1 $\pm$ 18.1 (WOMAC score)	81.8 $\pm$ 10.2 (WOMAC score)
Our Study	91.7	93.1

Table 6. Showing Mean Harris Hip Scores at 12 Months in the Comparable Clinical Studies

Functional Outcome of THR Patient after 36 Months

Functional Outcome of HRA Patient after 36 Months

ABBREVIATIONS

HRA: Hemiarthroplasty, THA: Total hip arthroplasty, POP: Plaster of Paris, HTN: Hypertension, ROM: Range of Movement, RTA: Road traffic accident, AVN: Avascular necrosis, COPD: Chronic obstructive airway disease, HHS: Harris Hip Score.

CONCLUSION

From our study, we have seen that both hemiarthroplasty and total hip arthroplasty are good treatment options for treatment of displaced femoral neck fractures in elderly. There is no significant difference in treatment of neck of femur fractures treated with THA and HRA in terms of functional results and intra- and post-operative complications. However, there is a statistically significant difference in intra-operative blood loss between the 2 types of procedures. The increased blood loss and longer operating time associated with THR did not increase the number of general complications or the mortality rate. Timing of surgery does not have any significant effect on final outcome.

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