

Cup Positioning in True or False Acetabulum in Total Hip Arthroplasty: Which one is More Effective: A Randomized Clinical Trial on Patients with Crowe type 3 and 4 Dysplastic Hip

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Abstract

Background and objectives: Hip dysplasia is a common hip disease which could be diagnosed in different ages and Total hip arthroplasty (THA) is a common surgical procedure for dysplastic hip in adults. Cup placement in patients with false acetabulum formation could be performed in true or false acetabulum. The current study aimed at evaluating and comparing the effectiveness of these two procedures in patients with Crowe type 3 or 4 dysplastic hip underwent THA.

Methods: In this randomized open label parallel group clinical trial 67 patients/71 hips with crowe type 3 or 4 dysplastic hip undergoing THA were assigned to Group 1: patients with cup placement in true acetabulum or group 2: patients with cup placement in false acetabulum. Severity of pain was assessed using visual analogue scale (VAS), range of motion (ROM), limb discrepancy, gait ability, need for repeated joint replacement and also Harris hip score. Data were collected and analyzed using SPSS software version 20.

Results: 67 patients/71 hips entered the current study with the mean age of 50.51 ± 9.94 years. Two study groups were comparable in terms of basic characteristics ($P > 0.05$). No significant differences were observed between two groups regarding mean values of VAS, ROM, limb discrepancy and Harris hip score ($P > 0.05$).

Conclusion: Cup placements in true or false acetabulum showed comparable effectiveness on all studied main orthopedics outcomes which are clinically important. We recommend more clinical trial studies with larger sample size for confirming our study results.

Introduction

Hip disorders like hip developmental dysplasia (DDH) account as prevalent orthopedic disease among children (1, 2). Epidemiologic studies revealed that hip developmental dysplasia is common in children with a prevalence rate of 0.5 to 4% based on diagnostic criteria (3). Defining as shallow acetabulum with defects in superior wall. Cases of hip developmental dysplasia are diagnosed in early ages by the means of physical examinations and ultrasound studies but some patients might also require future surgical interventions and some may be also missed due to mild clinical presentation during early adolescence (4) whom they refer to orthopedic clinics later complaining from symptoms and signs i.e. trendelenburg sign and claudication which require intervention (5, 6). Previous studies have indicated associations between early adolescent osteoarthritis and developmental hip dysplasia (7).

Crowe's classification is based on easily identifiable anatomic landmarks based on AP radiography of pelvis. Type III and IV are the most severe types of DDH (8). Imaging studies using computed tomography (CT) scan in patients with hip dysplasia indicated that the most common acetabular changes in patients with hip dysplasia include: increased anteversion angle, insufficient covering of femoral head, defects in anterior wall of acetabulum and shallow joint (9). Abnormal anatomical structures in hip is caused by inappropriate weight distribution on femoral head and acetabulum (10).

Early treatments of hip dysplastic diseases could prevent future osteoarthritis. But if the DDH is missed or ignored in infantile and early adulthood, the preferred treatment is THA. It has been declared that THA in patients with hip dysplasia induced osteoarthritis significantly increased the quality of life in patients (11). In dysplasia that form false acetabulum, femoral head is displaced to superior and lateral and anterior and superior acetabulum wall is defected. In these patients, muscles and soft tissue are highly contracted and the vast soft tissue release, capsulotomy and iliopsoas tendon release are required (12, 13). In dysplastic hips with false acetabulum formation ("highly dislocated hips"), THA could be performed in various techniques including positioning the cup of prosthesis in true (original) or false (dislocated) acetabulum or in the middle of both(14). Cup Positioning in true acetabulum has this advantage that could bring more anatomical reduction compared to Cup Positioning in false one and could bring more anatomical center of rotation for patient's hip. But In these cases, positioning of cup prosthesis in hypo plastic acetabulum could lead to less bone coverage especially in medial wall for applying prosthesis and therefore, imposing more pressure to bones and implants. So, smaller sized cup and subsequently smaller femoral head should be used that in turn could be associated with increased risks of cup loosening and post-operative dislocations. Besides smaller sized cup makes our ability to choose variable cups restricted and this is a technical limitation for the surgeon. True acetabulum cup positioning could require concomitant surgical procedures such as subtrochanteric or supra condylar osteotomy and femoral shortening and theoretically, more soft tissue releasing procedures associated with increased surgery time and blood loss .In studies that tries to place the acetabular cup in the true acetabulum, subtrochanteric or supra condylar osteotomy seemed necessary in almost 50% of patients (18). Although subtrochanteric femoral shortening osteotomy is described as a successful and reliable procedure and studies showed a low rate of non-union (15, 16), but risks of a concomitant surgery and possibility of nonunion must be noted.

Another commonly used surgical technique in patients with DDH is cup positioning in false acetabulum. Regarding the better bone stalk compared to true hypoplastic acetabulum, this procedure makes the possibility of using larger cups and femoral heads that could decrease the risk of post-operative dislocation. But this method could also be associated with slight changes in center of hip rotation axis (14). This procedure also requires shorter surgical time. Structural bone grafts are also used in cases with insufficient bone coverage. Different studies have compared efficacy of cup positioning in true or false acetabulum in patients with hip dysplasia and reported paradoxical results (17, 18).

In recent years, types of prosthesis and cup positioning techniques changed vastly and as a result, new studies should be performed to compare the efficacy of these procedures. To the best of our knowledge, very few previous clinical trials have been performed to compare the clinical outcomes of cup positioning in true or false acetabulum in DDH patients undergoing THA (15, 19). Most of the previous studies were performed as retrospective cohorts. We aimed to evaluate and compare, prospectively, the effectiveness and complications of two main popular cup positioning techniques for total hip arthroplasty in patients with high dislocated developmental hip dysplasia.

Methods And Material

Study design and participants

In this randomized open label controlled parallel groups clinical trial, among patients who attended to orthopedic clinic of Saadi and Kashani hospitals, affiliated to Isfahan University of Medical Sciences, Isfahan, Iran and undergone primary cementless THA between 2013-2018 and fulfilled our study inclusion criteria 67 patients/71 hips who consented to participate in the study were selected and randomized into two intervention groups, i.e. THA using cup positioning in true acetabulum technique or with cup positioning in false acetabulum technique. We included subjects with hip dysplasia at Crowe type III and IV according to the classification of Crowe (20) underwent THA. Crowe index is measured using an AP radiographs of the hip centered on pubic symphysis and including the iliac wings and indexes including: (1) the height of the pelvis; (2) the medial head-neck junction in the affected hip; and (3) the inferior margin of the acetabulum (the teardrop). Crowe score 1 is having less than 50% partial dislocation. Crowe score 2 is 50-75% partial dislocation while crowe score 3 is 75-100% partial dislocation. Type 4 is more than 100% partial dislocation (21). Other inclusion criteria were as absence of any other skeletal deformities, aged more than 18 years, hip dysplasia, having both true and false acetabulum in their hip and signing the written informed consent. We excluded those patients who refused to participate in the study, a history of pelvic trauma, previous pelvic surgery history of hip infection or tumor, lacks of data on main study outcomes during follow up, any affecting by unilateral or bilateral other CROWE types forms hip dysplasia, having neuromuscular diseases, lumbar spine stiffness (lumbar spine lateral curve $<15^\circ$) or severe spinal deformity.

Study procedures and outcomes evaluation

We used direct lateral approach for all patients that is performed without trochanteric osteotomy. All osteophytes and soft tissues that interfered with our procedures were removed. For Crowe type IV DDH patients, resection of the hypertrophic capsule and femoral head was performed to expose the true acetabulum and proximal femur. Bone cup surface contact was $>75\%$ in patients. Stability of cup and superolateral side of the rim were evaluated by the surgeon during the surgical procedures and structural bone grafts were used in cases of insufficient bone cup coverage along with efforts to place the prosthesis in the medial location. The used devices in most patients were Triology acetabular system, M/L taper prosthesis, Aqulad wedge femoral stem and Coralli total hip system. All patients received 1 g of cephalixin administered 40– 60 min prior to surgeries.

Placement at true acetabulum

All the surgeries were conducted by a single surgeon in lateral position using direct lateral approach. Soft tissue dissection is conducted carefully keeping in mind that neurovascular bundle may not be present at normal anatomic place. The femoral neck is resected at around 1 cm proximal to lesser trochanter.

Pushing down toward capsule and by direct palpation, the correct position of the true acetabulum is located. Although the precise position of acetabular component is well determined in preoperative radiographs, the whole process of finding the true acetabulum is monitored by image intensifier, after sufficient soft tissue dissection, the acetabulum is deepened and enlarged gradually with serial reaming at the desired angle of abduction and anteversion till anterior and posterior wall appear in order to fix a cement less component (size 40-44). After capturing a proportional press fit, the cup is tightened with long screws. (21). No structural bone grafts were used in this group.

Placement at false acetabulum

The direct lateral approach was used in each case. Joint capsulectomy, gluteal sling release, and iliopsoastenotomy was performed. The cup (range 44-52 mm) was implanted at the nonanatomic so called * False * position by reaming the acetabulum posteriorly and inferiorly. Two or three screws were used to augment primary stability of the cup. No additional stabilization such as femoral head auto graft, cage or ring was used to support the acetabulum.

Placement of femoral prosthesis

After the cup implantation, the femur was internally rotated 90° and the femoral canal was prepared using the dedicated reamer for the stem. First, we reamed the femoral canal until the maximum cortical contact was reached distally. Then conical and triangular reaming of the metaphysis was performed to prepare for the proximal sleeve. With trial seated in the femur, we measured the final vertical distance from femoral head to cup under constant and vigorous traction. If hip reduction with a femoral trial stem was impossible, a sub trochanteric or supra condylar osteotomy would be performed for femoral shortening.

Post operation assessments

Patients were visited by an expert orthopedist. All patients received antithrombotic prophylaxis using low-molecular-weight heparin (LMWH) (at half-dose 4–6 h after the procedure followed by full-dose the next day) postoperatively.

The severity of pain in patients was assessed daily using Visual Analog Scale (VAS) ranged from 0-10 in which no pain gets score (0) and highest pain gets score 10, during the period of hospitalization and an average score was obtained for each patient in both groups. We should note that patients were encouraged to conduct early mobilization and limb exercises in bed immediately after surgery, especially hip abduction function exercise. They walked with partial weight bearing for approximately 17 days, and then gradually progressive full weight bearing was allowed at 8-12 weeks after surgery. The immediate postoperative and most recent anteroposterior (AP) radiographs of the pelvis centered on the pubic

symphysis and including the iliac wings were obtained for all patients and repeated in the first- third- sixth months after the surgery and also one year after surgery. Leg length discrepancy (LLD) was measured as the difference in distance between the tip of the lesser trochanter and the inter-teardrop line. The acetabular component was considered loosened in presence of a change in alignment of $> 4^\circ$ or migration of > 3 mm in the radiographic evaluation (22). Range of motion (ROM) of the involved joints was assessed by physical examinations 1 year after the surgery and included hip flexion, abduction, adduction, external rotation and internal rotation. The average degrees were calculated. Harris hip score (HHS) was measured for each patient after one year of surgery. This score evaluates patients' pain, ability of walking, requirement of support when walking, distance for walking, claudication, sitting condition, ROM, ability of using the stairs, ability of using shoes or socks, gait, ability of using public transportation and scores from 0 to 100 (23). The other complications such as infection, need for revision and hip dislocation were assessed and evaluated during the 1 year study duration.

Basic data assessment on patients

We collected data from patients including age, sex, weight, height, body mass index (BMI) and involved side, Crowe type and also gait type. Patient's gait was evaluated using scoring from 1 to 6. Normal gait scored 6, mild claudication but no usage of cane scored 5. Patients with the ability of long walks with one cane and mild disability of walking without cane scored 4. Score 3 were patients with limitation of walking with one cane and serious problems when walking without cane or standing up for a while. Serious disability of walking with or without one cane scored 2 and walking for only 2-3 meters or disability of walking or requiring to use 2 canes scored 1 (24). Crowe's classification is based on easily identifiable anatomic landmarks based on AP radiography of pelvis. Type III and IV are the most severe types of DDH (8). Here patients with gait types 4 to 6 and Crowe types 3 and 4 were entered.

Statistical analysis

Continuous and categorical data were reported as mean \pm Standard deviation (SD) and frequency (percentage), respectively. Normality of continuous was evaluated using Kolmogorov-Smirnov test and Q-Q plot. Continuous data were compared between groups using independent samples t-test and analysis of covariance (ANCOVA). ANCOVA was used when adjustment is need for potential confounding variables. Categorical data were compared between groups using chi-squared or Fisher exact tests. All statistical analyses were performed by using SPSS 20 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.).

Results

A total number of 154 patients were screened, 42 patients did not met the inclusion criteria, 23 patients did not consent to participate in our study and 17 patients after careful examination before starting the study have been excluded because they had some comorbidities affecting the main study outcome

variable, finally 72 patients/76hips with unilateral or bilateral hip dysplasia entered the study. 5 patients went out in follow up. Finally data of 32 patients/34 hips in True and 35 patients/37 hips in false groups were analyzed. The CONSORT flow diagram of the patients is presented in Fig. 1.

Our study population consisted of 39 males and 28 females. Mean age of our patients was 50.51 ± 9.94 and the mean BMI of patients was $25.84 \pm 2.50 \text{ kg/m}^2$. Majority of study participants had single side limb involvements, 37 (55.2%) with right and 26 patients (38.8%) with left side involvements) and remaining (4 patients, 6%) had both side limb involvements (2 patients in true acetabulum group and 2 patients in false acetabulum group). The study groups are comparable in terms of basic characteristics and there were no statistically significant differences between them ($P > 0.05$) (Table 1).

Table 1
Basic demographic and clinical characteristics of patients in two study groups

Variable		True (n = 32)	False (n = 35)	P-value*
Age		48.18 ± 10.50	52.84 ± 8.91	0.06
Sex	Male	19 (59.4%)	20 (57.1%)	0.79
	Female	13 (40.6%)	15 (42.9%)	
BMI		26.43 ± 2.85	25.25 ± 1.96	0.05
Limb Involved side	Right	18 (56.25%)	19 (54.3%)	0.45
	Left	12 (37.5%)	14 (40%)	
	Both	2 (6.25%)	2 (5.7%)	
Crowe type	3	22 (68.8%)	24 (68.5%)	0.58
	4	10 (31.2%)	11 (31.5%)	
Gait type	4	5 (15.6%)	5 (14.3%)	0.64
	5	16 (50%)	16 (45.7%)	
	6	11 (34.4%)	14 (40%)	

*Resulted from independent samples-test and Chi-squared test for continuous and categorical data, respectively. Data are reported as mean \pm SD and frequency (percentage).

Evaluating the past medical history of patients showed that 9 patients had previous hip surgeries (5 cases of derotational hip osteotomy and 4 cases of pelvis osteotomy) referred due to false acetabulum formation being candidates for THA.

We compared all predefined main outcomes between two groups. Mean values of VAS were not statistically significant different between study groups and this result did not change after adjustment for age and BMI. Range of motion was not significantly different between groups ($P = 0.16$), this result was marginally changed after adjusting the confounding effects of age and BMI however it was not

statistically significant ($P = 0.065$). The mean HSS scores of two groups were compared and it was not statistically significantly different both before and after adjustment for confounders. Limb discrepancy and joint replacement also were comparable between two groups. Similar results were observed for all study main outcomes in subgroup analysis by gender (Table 2).

Table 2
Comparison of main study outcomes between two study groups

Variable	Total sample			Female			Male		
	True	False	P-value	True	False	P-value	True	False	P-value
VAS	3.40 ± 0.75	3.43 ± 0.66	0.86	3.03 ± 0.75	3.41 ± 0.79	0.73	3.47 ± 0.77	3.45 ± 0.60	0.94
ROM	43.15 ± 10.47	43.91 ± 9.79	0.16	42.31 ± 11.36	41.41 ± 11.17	0.24	43.62 ± 13.49	45.77 ± 9.07	0.42
limb discrepancy (cm)	2.93 ± 1.13	2.46 ± 1.01	0.09	2.69 ± 0.85	2.50 ± 1.16	0.64	3.10 ± 1.29	2.45 ± 0.94	0.07
Harris hip score	55.56 ± 18.52	48.75 ± 13.55	0.10	53.38 ± 15.89	50.67 ± 14.65	0.66	57.05 ± 20.41	47.21 ± 13.11	0.09

VAS: Visual analog scale, ROM: Rang of Motion. *Resulted from independent samples-test and Chi-squared (or Fisher exact) test for continuous and categorical data, respectively. Data are reported as mean ± SD and frequency (percentage).

The hospitalization duration of patients ranged between 2–4 days. The preferred anesthetic method for all patients was spinal anesthesia but total number of 17 patients in both groups also underwent general anesthesia due to longer surgical duration. One patients in the false acetabulum group and 2 patients in the true acetabulum group had radiologic signs of acetabular loosening after the procedures. They were managed by observational evaluations and had no significant clinical problem at the end of the study. No significant differences were observed between two groups regarding hospitalization duration, changing the anesthesia technique from spinal to general and radiologic acetabular loosening ($P > 0.05$). Two other patients in false acetabulum group and 3 patients in the true acetabulum group had prosthesis dislocation ($P = 0.63$) that were treated with closed reduction and observational strategies and didn't have redislocation. No structural bone grafts were used in both groups. Five patients in the true acetabulum group underwent subtrochanteric or supra condylar osteotomy that resulted in non-union in 1 case of subtrochanteric osteotomy within our one year follow-up. He was treated then with bone grafts from iliac crest that led to union within 18 months.

Within 1 year after the surgeries, 2 patients from false acetabulum and 2 patients from true acetabulum and 1 patient from bilateral THA had still claudication but they reported significant improvements compared to before surgeries. No heterotopic bone formation was seen in osteotomy site. No early or late

wound dehiscence of infection occurred. No patient had iatrogenic vascular injury to femoral artery and no patient required repeated surgeries except those with postoperative dislocation who underwent close reduction. Only one case in the true acetabulum group had paresthesia in the follow-ups that was improved spontaneously without any treatments.

Discussion

THA for treatments of hip dysplasia with false acetabulum formation could be performed as prosthesis positioning in true or false acetabulum. Here we aimed to investigate and compare clinical results and complications of these two procedures in patients with hip dysplasia (crowe score 3 and 4). The most annoying complication of THA is prosthesis dislocation. Studies have shown that smaller cups size is correlated with higher chances of dislocation during THA (25). But in this study no correlation was detected between this complication and cup positioning. Also in our study no differences observed between two groups regarding VAS, ROM, limb discrepancy, gait ability, need for repeated joint replacement and also Harris hip score.

We should explain that there is a higher bone mass in true acetabulum group but the medial wall and superolateral side of acetabulum space are weak that require structural auto-graft bones from femoral head. In the current study, no structural bone grafts were used. These complementary procedures are associated with more operation time and more surgical complications. Although there might be bone mass deficiency in superolateral, anterior and posterior side of acetabulum wall in false acetabulum group, but based on Zheng and colleagues (26), cup medicalization could provide proper bone coverage. If leg lengthening would be more than 4 cm after hip reduction, subtrochanteric or supra condylar shortening osteotomy is performed and extensive soft tissue release was avoided (27). This caused lowering the risks of dislocation in patients. It should also be explained that LLD correction during the surgery is easier in the false acetabulum group. Because surgeons could easily use a longer and more profitable stem but in the true acetabulum group, SROM femoral stem should be used and in some cases we need femoral shortening osteotomy which is an additional surgical procedure to THA.

Previous studies have evaluated different surgical techniques for THA (28). In a study by Widmer in 2007, zones of cup placements were evaluated in patients undergoing THA and indicated that most patients have good coverage and symmetric load transfer and therefore, leading to good long term stability. Cup placements in true or false acetabulum had almost same prognosis in patients. It was also recommended that a safe zone should be considered (29). These results are in line with our study indicating no significant difference between cup placements. We believe that long term follows up of patients might be required in order to gain more accurate results. In a systematic review performed by Seagrave and colleagues in 2017, 28 previous articles were assessed in order to determine a safe zone for cup placement during THA. They concluded that justifying a safe zone is almost not possible due to variable results in previous studies and there might be no significant differences between surgical methods due to multifactorial nature of THA dislocation. They also recommended that more studies should be performed comparing cup positioning and dislocation rates (30). These results are in line with

our findings showing no significant differences in rates of dislocation in both groups. Based on previous studies, small size of femoral head (lower than 22 mm), soft tissue tension and higher ages could increase risks of dislocation after THA. Higher risks of dislocation in true acetabulum could be also due to this issue that >70% cup coverage must be achieved during THA and for this matter and also due to hypoplastic, shallow, and bone deficient cup in these patients, smaller size of femoral head should be placed. However we showed no significant higher dislocation in true acetabulum group. The possibility of dislocation in false acetabulum group could be also increased due to the changes in center of hip rotation axis. Further studies on larger populations and long-term follow ups are required to investigate the risks of dislocations. The position of true acetabulum restricted the choice of acetabular cup and liner used by the surgeon.

Small amounts of lateralization in acetabular components are observed in false acetabulum group in some studies. This could increase the chances of reduction in average ROM and HHS and limitation in abduction or improving femoroacetabular impingement in this group. Here we observed no significant differences in HHS and average ROM femoroacetabular impingements between groups. But on the other hand, we observed 3 cases of claudication and positive post-operative trendelenburg sign after one year study in the false acetabulum group and one case in true acetabulum group. It should also be noted that the gait type score of these 3 patients were also higher before surgeries (two cases had 5 scores and 2 cases had 6 scores).

Murayama and colleagues investigated radiological and clinical results of THA for patients with type 1 to 3 crowe hip dysplasia. They assessed 43 hips and reported that moderate high cup placement without bulk bone grafting at a horizontal locus more medial than that of a normal hip is associated with better prognosis (31). These findings are not in line with our results and we believe it is due to differences in the study population. We investigated patients with crowe type 3 and 4 while they performed their study on patients with type 1 to 3 crowe hip dysplasia. In the study by Stans and colleagues, they evaluated 90 hips in 82 patients undergoing THA for crowe type 3 hip dysplasia. They indicated that 25.7% of cups had been placed in false acetabulum. They indicated that 83.3% of cups which had been placed in false acetabulum had loosening while on the other hand, 42.3% of cups in true acetabulum had loosening. Finally, they suggested that cup placement in true acetabulum might bring better beneficial effects for patients with hip dysplasia undergoing THA (32). These results are somehow not in line with our study. We observed no significant difference between the two surgical methods. This variation could be due to differences in study population and method. Here we included patients with crowe type 3 and 4 and evaluated a vast variety of clinical factors while on the other hand, Stans et al included only patients with crowe type 3 and evaluated their loosening based on radiographic criteria.

The important point of our study is that we evaluated hip function and clinical features of patients such as HHS, VAS, and ROM, limb discrepancy, gait ability and need for repeated joint replacement which all of these outcomes are clinically important and they are associated with patient's satisfaction but former studies have mostly focused on radiologic features such as loosening. The limitations of the current study is small sample size and lack of measuring peri-operative complications including bleeding,

surgery/anesthesia duration. We also followed up patients for only one year and more studies with longer follow up are needed. Another limitation is that all of the surgeries in this study was performed by one orthopedic surgeon in a trauma center in which THAs are performed in large scales. In a Canadian study it was stated that surgeons who performed over 35 THAs per year had a lower dislocation rate than surgeons with smaller volumes (33). This issue could have influenced our results and we believe that other studies should include results of younger and less experienced surgeons. Another limitation of the current study could be not documenting different types of prothesis used for surgeries and not evaluating them. Also there is no specific criteria for choosing among these different devices.

Conclusion

The mainstone of our study is that we evaluated clinically important outcomes i.e HHS, VAS, and ROM, limb discrepancy in dysplastic hips underwent THA in two groups. Comparison of VAS, ROM, limb discrepancy, gait ability, need for repeated joint replacement and also Harris hip score in our clinical trial study showed that no significant differences were observed between these patients. We also showed no significant differences between patients regarding hip dislocation, repeated surgeries and cup loosening however, higher rates of subtrochanteric or supra condylar osteotomy was performed in true acetabulum group. Based on our results, choosing between true or false acetabulum placements depend on the experience of the surgeon and his ability to perform each of these procedures. No significant clinical advantages was observed between two mentioned techniques. Former studies showed same results but yet, some paradoxical results were reported. These differences were mostly due to study design and populations and we recommend that more clinical trial studies on larger populations with longer follow-up durations based on clinically significant outcomes should be performed.

Abbreviations

THA Total hip arthroplasty

AP anterior-posterior

DDH developmental dysplasia of hip

VAS visual analogue scale

LLD leg length discrepancy

ROM range of motion

HHS Harris hip score

BMI body mass index

SD standard deviation

Declarations

Ethics approval and consent to participate:

The study protocol was approved by Ethics Committee of Isfahan University of Medical Sciences with the code of: IR.MUI.MED.REC.1397.072. (Iranian Registry for Clinical Trials (IRCT) code: IRCT20200217046523N5) and all participants signed the written informed consent to participate in this study.

Consent for publication:

I, the undersigned, give my consent for the publication of identifiable details, which can include photograph(s) and/or videos and/or details within the text ("Material") to be published in the above Journal and Article. Therefore, anyone can read material published in the Journal.

Availability of data and materials: The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Competing interests:

Not applicable.

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Authors' contributions:

Mehdi Motifard: Substantial contributions to the conception or design of the work, Drafting the work, Final approval of the version to be published, Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Saeed Hatami: analysis, or interpretation of data for the work, Drafting the work or revising it critically for important intellectual content, final approval of the version to be published.

Moslem Rafiee: Drafting the work or revising it critically for important intellectual content, Final approval of the version to be published, Agreement to be accountable for all aspects of the work in ensuring that

questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Arash Toghiani: Substantial contributions to the conception or design of the work, Drafting the work, Final approval of the version to be published, Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ali Andalib: analysis, or interpretation of data for the work, Drafting the work or revising it critically for important intellectual content, final approval of the version to be published.

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Figures

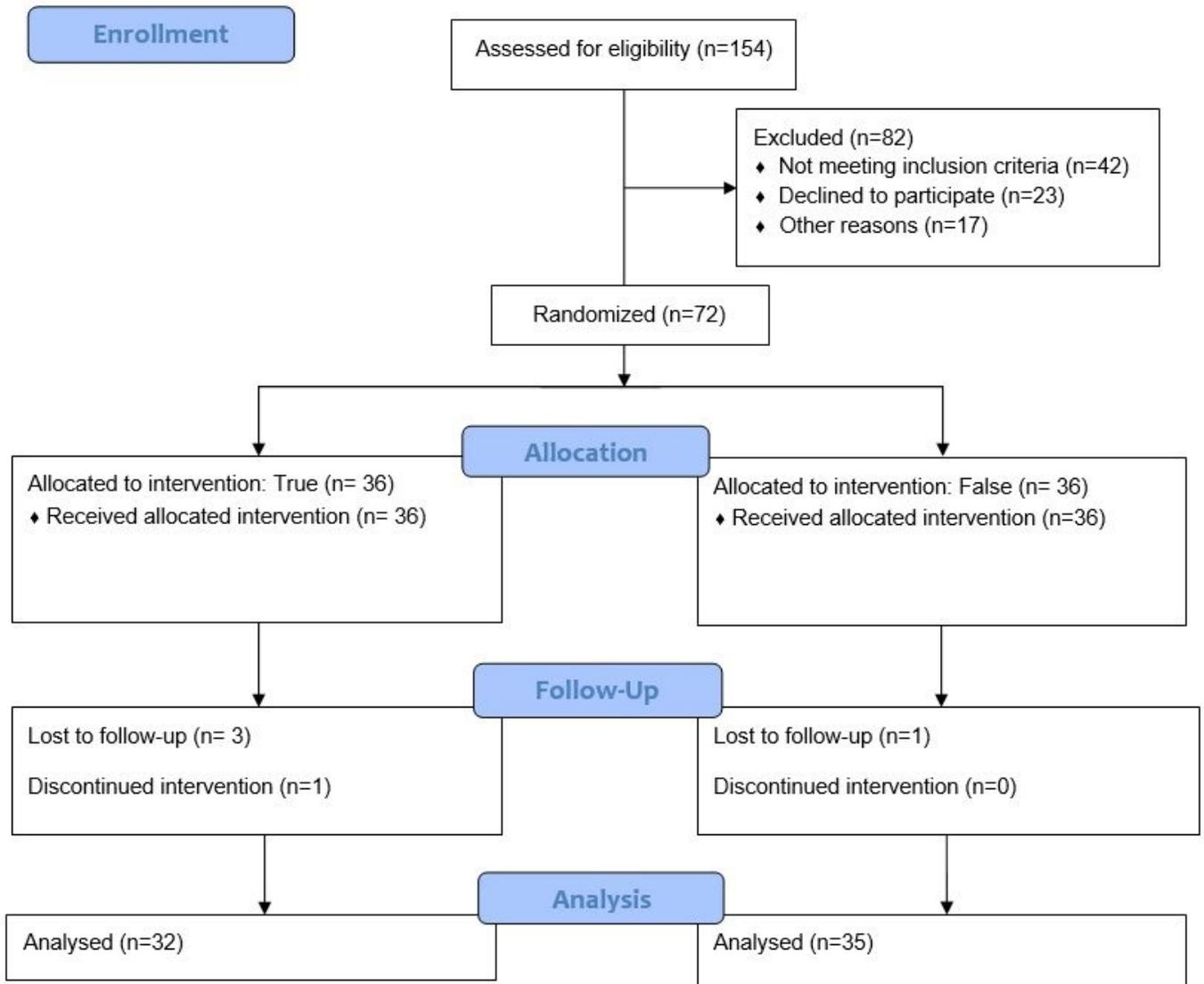


Figure 1

The CONSORT flow diagram of the patient's recruitment.