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ORIGINAL ARTICLE

Comparison of the Efficacy of Aspirin with Rivaroxaban in Postoperative DVT Prophylaxis after Hip Arthroplasty in patients at tertiary care hospital, Karachi

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ABSTRACT

Background: Patients suffering from severe hip arthritis and osteonecrosis are increasingly turning to total hip arthroplasty (THA) as a treatment option, according to recent research. If deep vein thrombosis (DVT) is not treated properly, it can result in a life-threatening pulmonary embolism as well as other potentially life-threatening consequences (PE).
Aim: To compare the efficacy of aspirin with rivaroxaban in postoperative dvt prophylaxis after hip arthroplasty in patients at tertiary care hospital, Karachi
Methodology: The College of Physicians and Surgeons of Pakistan approved this study prior to its completion. The Department of Orthopedics at JPMC, Karachi, chose those who had complete hip arthroplasty for the study. The school's ethical committee approved the study before it could begin. Before participating in the trial, all patients signed an informed consent form granting them permission to do so.
Results: Patients from JPMC Karachi's Department of Orthopedics were included in the study. They were aged 49 to 75. Travel time to the hospital was an average of 58.878.19 years. They were aged 49 to 75. For every month, hour, and day spent in hospital, there are 14.416.14. Eighty people used aspirin, 32(40%) were 40-60 and 48(60%) were 61-75. In the rivaroxaban group, 40 patients (50%) were 40-60, and (61-75). The aspirin group had 80 patients, 38 male (47%) and 42 female (42%) (52.5%). One hundred and twenty-five patients (68.8%) were on rivaroxaban (31.2%).
Conclusions: People who have a spontaneous venous thromboembolism should not be given long-term thromboprophylaxis after taking oral anticoagulants until more research is done. It is very important to figure out what DVY risk factors are in order to come up with preventative measures that are both safe and affordable. People can live longer if they get an early diagnosis and get treatment quickly, so they can live longer. High-quality, large-scale studies must be done before a conclusion can be drawn.
Keywords: DVY risk, thromboembolism, thromboprophylaxis, arthroplasty

INTRODUCTION

Patients suffering from severe hip arthritis and osteonecrosis are increasingly turning to total hip arthroplasty (THA) as a treatment option, according to recent research. If deep vein thrombosis (DVT) is not treated properly, it can result in a life-threatening pulmonary embolism as well as other potentially life-threatening consequences (PE). 2 Even though thrombi can form in the veins of the arms, the lower leg is the most likely site for DVT to develop. In contrast, this disease affects 5.3% of Asian countries such as China, 15.8% of Asian countries such as Japan, and 12.5% of Asian countries such as Pakistan, among others. Despite the presence of discomfort, swelling, and redness, as well as superficial dilated veins and a low-grade temperature on the skin, the deep veins in 20% of patients with clinical signs and symptoms of DVT are found to be normal, according to the findings.

When venous stasis, hypercoagulability, and endothelial damage all occur at the same moment as thrombi are generated, this is referred to as a triple thrombotic event. Risk factors for deep vein thrombosis include being immobilised or unmoving for more than 72 hours, undergoing surgery for more than 2 hours, having a malignancy, being overweight or suffering from other ailments. 8 A critical component of patient care is the prediction and prevention of post-operative deep vein thrombosis by providing prophylaxis to patients who have been recognised as at risk due to the presence of specific risk factors. 9 Patients who have undergone a large surgical treatment are prone to have deep vein thrombosis (DVT). Doppler ultrasonography is one of the diagnostic methods available for the diagnosis of deep vein thrombosis (DVT) (DVT). It's non-invasive, inexpensive, and simple to recreate if necessary, making it a win-win situation. The sensitivity and specificity for identifying proximal DVT are comparable to those of venography, and there are no dangers associated with using it. Patients undergoing orthopaedic surgery are advised to take low-molecular-weight heparin (LMWH), fondaparinux (which inhibits activated factor XA), aspirin, and other anticoagulants, according to current recommendations. Despite having the same antithrombotic efficiency as LMWH, rivaroxaban is associated with a higher risk of hemorrhagic events and wound complications when compared to LMWH. 13 One multicenter, double-blind, randomised study found that the incidence of symptomatic DVT ranged from 30% to 80%, but that the prevalence of nonsymptomatic DVT varied between 0.5 and 4%.

After ten randomised controlled studies, it was determined that extending aspirin prophylaxis following hip or knee arthroplasty was statistically insignificant. 14 In the Huang et al trial, which looked at patients who received DVT prophylaxis for 21 days with the two drugs, the effectiveness rates for asprin and rivaroxaban were 83.3% and 84.9%, respectively, based on the two medications' effectiveness. 15 Intends: The purpose of this study is to evaluate the efficiency of aspirin and rivaroxaban in postoperative DVT prophylaxis after hip arthroplasty in order to develop a local perspective on the effectiveness of these medications. Studies have shown that aspirin and rivaroxaban are effective in the prevention of deep vein thrombosis (DVT), although the results have been ambiguous and few in number so far. 12-15 Low-income countries may benefit from low-cost aspirin prophylaxis to prevent cardiovascular disease.

This study's results are expected to aid in the creation of new recommendations for the early detection of DVT and the routine administration of DVT prophylaxis in the medical community, according to the researchers. Reduced hospitalisation time, improved patient outcomes, as well as increased financial and psychological benefits for the patient, are all projected as a result of the implementation of this programme.

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MATERIALS AND METHODS

It was a Randomized control trial. Study was conducted at Department of Orthopedics, JPMC, Karachi. Calculation of sample size was done by using WHO software where, Alpha=5%, Power of the test 1-beta=80, taking efficacy in asprin (83.3%) and rivaroxaban (84.9%).15Thus calculated sample size was n=17035. Since review of literature showed no other study from which a lower sample size could be calculated and calculated sample size is not achievable we took a sample size of 160 patients i.e., 80 patients in each group.

Inclusion criteria:

- Patients presenting with osteoarthritis undergoing total hip arthroplasty on the basis any one or more of the following criteria were included.
- Osteoarthritis confirmed on X-ray (nonuniform joint space loss, osteophyte
  formation, cyst formation and subchondral sclerosis).
- Pain not responding to analgesics or antiinflammatories for more than 6 months.
- Daily living activity limitation usually your free time activities, sport or work for more than 6 months.
- Pain keeping the patient awake at night for more than 6 months.
- Either gender
- ASA ≤ 2.
- Age 40-70

Exclusion criteria:

- Non-consenting. Patients with history of anticoagulation therapy like aspirin, warfarin and enoxaparin.
- Patients with history of previous total hip orknee arthroplasty.
- Patients with history of hypo or hyperthyroidism.
- Patients with history of pulmonary embolism.
- Patients with history of malignancy or on treatment for malignancy like lung, pancreatic and renal carcinoma.
- Patients with history of varicose veins.
- Patients with history of blood transfusion within one week.
- Patients with history of renal impairment, chronic obstructive pulmonary disease, congestive heart failure and chronic liver disease will be excluded.

Data collection procedure: The Pakistani College of Physicians and Surgeons gave their approval. Patients who received total hip arthroplasty at the JPMC Orthopedic Department in Karachi were eligible to participate in the study. Before the study could begin, it needed to be approved by the institution's ethics review board. Before receiving samples, all patients gave their informed consent, and their data was used in the research process. Patients gave a brief description of their personal qualities when they initially came. They were also quizzed about their age, gender, and any medical issues they could have. A wall-mounted tape was used to measure each person's height. People's weight was measured to the nearest pound on a weighing machine when they were admitted to the hospital for surgery and their BMI was calculated. Patients were given aspirin and rivaroxaban in opaque envelopes with the initials A and R on them at random. Before surgery, all of the patients were given equal-length quadriceps muscle contractions as well as ankle joint flexion and extension to prevent deep vein thrombosis (DVT). An ultrasound of the lower limb veins was conducted prior to the surgery. This category contained the deep femoral vein, the superficial femoral vein, the popliteal vein, the anterior tibial vein, the posterior tibial vein, and the peroneal vein. In front of the researcher, an orthopaedic surgeon with more than five years of experience performed on both groups of patients. Following surgery, both groups of patients got subcutaneous injections of enoxaparin 2000 U. These injections were given once a day for five days following surgery. After stopping enoxaparin, individuals in Group A were given 100 mg of aspirin every day for 16 days. Patients in group R began taking rivaroxaban 10 mg daily for the same amount of time as those in group S after quitting enoxaparin on day 5. Both groups will have a duplex ultrasound scan on both lower limbs after 21 days of treatment. The study will be led by an expert sonologist and the researcher will be present at all times for all patients in the trial. A paper with all of the information on quantitative and qualitative features was attached (such as patient age and length of stay in the hospital, surgical time, and osteoarthritis duration). This study includes both quantitative and qualitative data (gender, residence, hypertension, diabetes mellitus type II and dyslipidemia).

Data analysis procedure: SPSS Version 16 was used to look through the data. Means and standard deviations were found for things like age, length of stay in the hospital, operation time, and osteoarthritis duration. There are a lot of qualitative variables that have frequencies and percentages. Gender, hypertension (high blood pressure), diabetes mellitus type II, dyslipidemia, smoking, obesity, job, side of hip arthroplasty, and efficacy (yes/no) are some of them. Tests like the Chi-square one were used to compare how well two groups were at something. It was used to see how effect modifiers changed the outcome variable called efficay by looking at how people were grouped by things like age and gender, where they lived and what kind of hypertension, diabetes, and dyslipidemia they had, as well as how much weight they had and what side of their hip arthroplasty they had. After stratification, the chi-square test was used and a p-value of 0.05 was considered to be important.

RESULTS

People who underwent total hip arthroplasty at the JPMC in Karachi and met the inclusion and exclusion criteria were included in this study. Among the aspirin-taking patients, at least half were under the age of 50. Aspirin was taken by at least 75 persons in the group. In our study, the average age was 58.878.19 years old, and the average time spent in the hospital was 1.870.78 hours and 2.78 days. Rivaroxaban was taken by 80 participants between the ages of 49 and 75 at the time of the study. Our study included 59.449.85 people, 14.416.14 months of OA, 1.410.14 hours of surgery, and 4.412.14 days of follow-up. The average age was 39.5 years. Of the 80 patients who used aspirin, 32 (40%) and 48(60%) were aged 40-60 and 61-75, respectively, according to the results of this study. People in the rivaroxaban group were only 40 and 40% of the population between the ages of 40 and 75, respectively. According to a study, women comprised 47.5% of the aspirin group, while males comprised 52.5% of the group. When the rivaroxaban group had 80 persons, 55 were men (68.8%) and 25 were women (31.2%). More than seventy percent of the 80 people who used aspirin resided in cities; only twenty-one lived in rural areas. For comparison's sake, only 36 of the 80 patients taking rivaroxaban were city or rural dwellers. Only 42(52.5%) of the 80 persons who took aspirin had osteoarthritis for less than 24 months and 38(47.5%) had it for more than 24 months. The rivaroxaban group included 80 participants, 44 of whom had the condition for less than 24 months, and 36 of whom had the disease for more than 24 months. Table 5 demonstrates this. Forty-one of the eighty patients in the aspirin group had surgeries lasting less than or equal to two hours. Thirty-five (43.8%) and 45(56.2%) of the 80 rivaroxaban patients underwent surgery for less than two hours and for more than two hours respectively. More than half of the participants who took aspirin had hip arthroplasty on the right and left, respectively. The rivaroxaban group saw 42(52.5%) and 38 (47.5%) persons undergo right and left arthroplasty, respectively, whereas there were 80 participants in the group. One-third of those taking aspirin were diabetics with type II diabetes; the other three-fourths of those taking aspirin weren't. A total of 80 patients were treated with rivoxaban; of these, 17(21.2%) had diabetes mellitus type II, while 63 (70.8%) did not. Table 8 demonstrates this.

People who took aspirin had a 40% higher rate of hypertension, while those who didn't took aspirin had a 60% higher rate. A total of 23 of the 80 participants in the rivaroxaban group (28.8%) had hypertension, whereas the other 57% (71%) did not.

Aspirin-induced dyslipidemia was found in 36 out of 80 patients. Others, though, did not. In the rivaroxaban group, 35 (43.8%) had dyslipidemia, whereas 45 (56.2%) did not. A total of 32 smokers and 48 nonsmokers took aspirin in the study, which included 80 persons. In the rivaroxaban group, there were 80 participants, of which 18(22.5%) smoked and 62(77.5%) did not. 35(43.8%) of the 80 participants who took aspirin had obesity, while 45 (56.2%) did not. In the rivaroxaban study, there were 80 participants, and of those, 18%, 18.8%, 81.2% and 81.2% had obesity, respectively. If you're taking aspirin, you are more likely to be at work or not at work than if you aren't. On the other hand, 47 of the 80 patients in the group taking the medication rivaroxaban had both a job and no job. Aspirin and rivaroxaban were shown to be efficacious in 92.5 and 93.8% of the participants, respectively. The P-value was found to be. 75. A total of 30 (93.8%) and 37 (92.5%) of the 45-60-year-olds in the aspirin group and the rivaroxaban group used aspirin, respectively. The score was 0.83. When it comes to efficacy, however, studies with aspirin and rivaroxaban found that 44 (91.7%) and 38(95%) of the participants in the 61-75-year-old age range had positive results. The p-value was 0.53%. Based on their efficacy, aspirin and rivaroxaban were divided into male and female groups. More than half of the males in the aspirin group had a positive effect. There was a P-value of 0.01. Aspirin and rivaroxaban were found to be more efficacious in females than in males. Of the females in each group, 38 (90.5%) and 20(80%) received an effective treatment. After taking the medication, 50 of 53 persons in the aspirin group and 33 of 33 people in the rivaroxaban group recovered. The significance level was set at 0.76. Both aspirin and rivaroxaban were highly effective in rural patients, however only 21(100%) and 42(95.5%) of those patients resided in cities or towns, respectively. There was a P-value of 0.01. People with osteoarthritis who had it for less than 24 months responded well to aspirin and rivaroxaban. A total of 38(90.5%) and 39(88.6%) of these persons had positive outcomes. There was a P-value of 0.78. Patients with osteoarthritis who had been taking aspirin or rivaroxaban for more than 24 months exhibited efficacy in both groups, 94.7% and 100%, respectively. There was a P-value of 0.01. A 95% success rate was seen in those who took aspirin or rivaroxaban before surgery, while the success rate was 100% in those who waited until after surgery to take either medication. The significance level was set at 0.01. There was a 90% efficacy rate for aspirin and rivaroxaban in the patients who underwent surgery for more than two hours, respectively, in the two groups. This study had a p-value of 0.86. Patients who received right hip arthroplasty versus left hip arthroplasty in the aspirin and rivaroxaban groups had a higher success rate. The significance level was set at 0.87. After surgery, both aspirin and rivaroxaban had an effect on one side of the hip joint. 40 (90.9%) of those who took aspirin experienced side effects, as did 35 (92.1%) of those who underwent surgery on the left side. There was a P-value of 0.84%. 34 and 17 patients with type II diabetes were affected by aspirin and rivaroxaban, respectively. There was a P-value of 0.01. Both aspirin and rivaroxaban were effective in treating diabetes mellitus type II, however only 40 and 58 patients who did not have diabetes were affected.

Type II diabetes, then. There was a p-value of 0.83. Aspirin and rivaroxaban were shown to be beneficial in treating high blood pressure in 30 (93.8%) and 21 (91.3%) of the individuals who took them, respectively. To put it simply, the P-value is 0.73. In the groups of patients without hypertension, aspirin and rivaroxaban demonstrated efficacy, but not in the groups of patients with hypertension. The significance level was set at a 0.05 level (P = 0.52). Aspirin and rivaroxaban were categorised into two categories based on their efficacy for patients with dyslipidemia.. Thirty-three (91.7%) and thirty-five (100%) of the patients with dyslipidemia were successful in both groups. There was a P-value of 0.01. 93.2% of those using aspirin who did not have dyslipidemia were found to be effective. 80.9% of those in the group taking rivaroxaban had no dyslipidemia. The p-value was 0.57%. There were two groups for the aspirin group and the rivaroxaban group: those who smoked and those who didn't, respectively. Thirty-two (100%) and thirteen (72.2%) of the patients who smoked in the aspirin group were affected. There was a P-value of 0.01. Patients who did not smoke had a higher success rate with aspirin and rivaroxaban medication than those who did. There was a P-value of 0.01. Aspirin and rivaroxaban were shown to be effective in 94.33% and 100% of obese patients, respectively, according to the results of the study. There was a P-value of 0.01. A total of 41 (91.1%) and 60 (92.3%) of the individuals in the aspirin group who were not obese were found to be effective in the study. The rivaroxaban group had the same problem. Percentage points (P) were 0.82. The effectiveness of aspirin and rivaroxaban was separated into two groups. There were 38(90.5%) of the patients in the aspirin group) and 42(89.4% of the patients in the aspirin group) employed. This study had a p-value of 0.86. Aspirin and rivaroxaban groups showed that 36 (94.7%) and 33(100%) of patients who were unemployed had efficacy, but not in the aspirin or rivaroxaban groups. There was a P-value of 0.01.

Table 1: Descriptive statistics Aspirin group vs Rivaroxaban group

Variable	Mean ± SD	Standard deviation	Min-Max
Age Aspirin group (years)	58.87	±8.19	49-75
Age Rivaroxaban group (years)	59.44	±9.85	49-75
Duration of OA Apirin group (months)	13.87	±4.78	10-24
Duration of OA Rivaroxaban group 1(months)	14.41	±6.14	10-24
Duration of surgery Aspirn groups (hours)	1.87	±0.78	1-3
Duration of surgery Rivaroxaban group (hours)	1.41	±0.14	1-3
Length of hospital stay Aspirin group (days)	3.87	±2.78	2-7
Length of hospital stay Rivaroxaban group (days)	4.41	±2.14	2-7

Table 2: Gender distribution

Gender	Aspirin group	Rivaroxaban group
Male	38 (47.5%)	55 (68.8%)
Female	42 (52.5%)	25 (31.2%)
Total	80 (100%)	80 (100%)

Table 3: Side of hip arthroplasty in aspirin group (80) versus rivaroxaban group (80)

Side of hip arthroplasty	Aspirin group	Rivaroxaban group
Right	36 (45%)	42 (52.5%)
Left	44 (55%)	38 (47.5%)
Total	80 (100%)	80 (100%)

Table 4: Efficacy in aspirin group (80) versus rivaroxaban group (80)

Groups	Efficacy		P-value
	Yes	No	
Aspirin	74 (92.5%)	06 (7.5%)	0.75
Rivaroxaban	75 (93.8%)	05 (6.2%)	0.75

DISCUSSIONS

Apart from being a serious complication, VTE makes a major contribution to perioperative mortality as well as unexpected deaths in hospitals. The increased coagulability of blood may persist for up to four weeks following total hip arthroplasty, and the

increased risk of postoperative deep vein thrombosis (DVT) may persist for up to three months after the procedure. Certain writers have looked into the possibility of continuing prophylaxis after major orthopaedic surgery because the vast majority of VTE incidences occur in patients who have been discharged from the hospital. The prevention period should be extended for all patients undergoing major orthopaedic surgery as a result of multiple studies showing that prolonged prophylaxis significantly reduces the risk of VTE in the long term. It is recommended that patients undergoing total hip arthroplasty take LMWH, fondaparinux, which inhibits activated factor Xa, and aspirin in order to reduce difficulties following the procedure. These medications should be taken for a minimum of 10–14 days after the treatment is completed. We included 160 individuals who had undergone total hip arthroplasty in our research. In compared to the general population, the aspirin group had a mean age of 58.878.19 years, an average OA length of 13.874.78 months, an average operation time of 1.870.78 hours, and an average hospital stay duration of 3.872.78 days. According to the data, the average age of the study's rivaroxaban-treated group was 59.449.85 years, the average length of osteoarthritis (OA) was 14.416.14 months, the average amount of surgery was 1.410.14 hours, and the average length of hospitalisation was 4.412.14 days. Aspirin and rivaroxaban had 74 (92.5%) and 75(93.8%) participants who shown efficacy in the respective studies. The p-values were found to be 0.75 in this study. A total of 399 participants expressed an interest in participating in the study. Patients were divided into even and odd groups based on the last digit of their registration number. We divided the aspirin sample into two equal groups, one for persons with odd numbers (n=198) and the other for participants with even numbers (n=192), and then analysed the results. All patients received enoxaparin subcutaneous injections immediately following the operation, which continued until the fifth postoperative day after the procedure was completed. A total of 16 days of thromboprophylaxis with 100 mg of aspirin once daily was administered to the patients in the aspirin-treated group. The oral rivaroxaban group received thromboprophylaxis with 10 mg rivaroxaban once daily for an additional 16 days, which was shown to be effective. For 90 days, the signs and symptoms of VTE as well as bleeding concerns were observed. The rates of VTE were similar in the aspirin and rivaroxaban groups (6.6% and 5.7%), respectively) (P = 0.83, respectively). In the aspirin group, two percent of patients experienced serious bleeding events, whereas only one patient (0.5%) in the rivaroxaban group experienced major bleeding events (P = 0.01). Five patients (2.5%) in the aspirin group experienced major bleeding, whereas six patients (3.1%) in the rivaroxaban group experienced major bleeding as well as clinically meaningful nonmajor haemorrhage (P = 0,77), respectively. During the 90-day follow-up period, one patient in the aspirin group (0.5%) developed a pulmonary embolism, but none in the rivaroxaban group (P = 1.0). 137

CONCLUSIONS

People who have a spontaneous venous thromboembolism should not be given long-term thromboprophylaxis after taking oral anticoagulants until more research is done. It is very important to figure out what DVY risk factors are in order to come up with preventative measures that are both safe and affordable. People can live longer if they get an early diagnosis and get treatment quickly, so they can live longer. High-quality, large-scale studies must be done before a conclusion can be drawn.

Conflict of interest: Nil

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