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Original article

Pneumatic compression device does not show effective thromboprophylaxis following total knee arthroplasty in a low incidence population

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ABSTRACT

Introduction: Purpose of this study was to assess whether the intermittent pneumatic compression (IPC) device would be an effective prophylaxis for deep vein thrombosis (DVT) following total knee arthroplasty (TKA) in a low incidence population.
Hypothesis: The mechanical thromboprophylaxis could reduce the incidence of DVT compared to non-prophylaxis group and would have similar efficacy as the chemoprophylaxis following TKA in a low DVT incidence population.
Materials and methods: From January 2009 to June 2016, 1259 elective primary TKA with preoperative diagnosis of primary osteoarthritis in a single institute were enrolled. Patients were divided into three groups: those who were managed with chemoprophylaxis (CPX group, 414 cases), with mechanical prophylaxis (IPC group, 425 cases), or without pharmacological and mechanical prophylaxis (control group, 420 cases). All patients underwent preoperative ultrasonography and computed tomographic venography on postoperative day 6 to assess development of DVT. The incidence of overall, proximal, symptomatic DVT and symptomatic pulmonary embolism (PE) were compared among the groups. Major and minor bleeding complications were also evaluated.
Results: The incidence of overall DVT was 14.8% in control group, 6.3% in CPX group and 11.3% in IPC group respectively and CPX group showed significantly lower incidence than other two groups ($p < 0.001$). The incidence of proximal DVT was 1.9% in control group, 0.7% in CPX group and 0.9% in IPC group respectively ($p > 0.05$). The incidence of symptomatic DVT was 0.7% in control group, 0% in CPX group and 0.7% in IPC group respectively ($p > 0.05$). There was no case of symptomatic PE diagnosed during hospital stay in all patients.
Discussion: Single use of IPC device could not reach significant level of DVT prophylaxis compared to control group and only chemoprophylaxis showed significantly reduce the incidence of overall DVT following TKA. Single use of IPC device does not show effective thromboprophylaxis in a low DVT incidence population.
Level of evidence: III, case control study.

1. Introduction

Total knee arthroplasty (TKA) is known for high risk of venous thromboembolism (VTE) which has been a major perioperative complication in Western countries [1]. Western guidelines have recommended using chemoprophylaxis following TKA. However, as using chemoprophylaxis, surgeons should concern perioperative bleeding that may lead to hematoma, hemarthrosis, wound dehiscence, skin necrosis, deep infection or hemodynamic problems [2]. Therefore, recent guidelines recommended a mechanical thromboprophylaxis in patients with high risk of bleeding or as an adjunct to anticoagulant-based prophylaxis to lower the above complications [1,3,4]. Meanwhile, prevalence of VTE in Asian population has been much lower than that of Western population [5,6]. Moreover, several studies suggested that routine chemoprophylaxis would not be necessary for prevention of DVT in a low incidence population

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when considering its benefit and safety [5,7–9]. Although mechanical thromboprophylaxis have been studied [7,10–12], there has been a paucity regarding efficacy of pneumatic compression device compared to chemoprophylaxis or even without prophylaxis following TKA in Asian population.

The purpose of this study was to assess whether the mechanical thromboprophylaxis would be an effective prophylaxis for DVT following TKA in this population. We hypothesized that the mechanical thromboprophylaxis could reduce the incidence of DVT compared to non-prophylaxis group and would have similar efficacy as the chemoprophylaxis following TKA in a low DVT prevalence population.

2. Materials and methods

2.1. Patients demographic characteristics

From January 2009 to June 2016, 1547 consecutive primary TKAs were evaluated. Only patients with a primary osteoarthritis who have undergone elective TKA using a conventional technique were considered for inclusion. The exclusion criteria included patients with diagnosed chronic or acute DVT preoperatively, patients with no postoperative computed tomographic venography (CTV) and patients with active bleeding, documented congenital or acquired bleeding disorders such as end-stage renal disease (ESRD), Von Willebrand disease, hemophilia, inflammatory diseases such as rheumatoid arthritis or secondary osteoarthritis. Computer-assisted surgeries such as navigation- or robot-assisted TKAs were also excluded since TKA without intramedullary instrumentation may affect the prevalence of postoperative DVT [13,14]. In addition, patients who had used anticoagulant before surgery for the treatment of various cardiovascular diseases such as myocardial infarction and ischemic stroke were excluded from this study. Therefore, a total of 1259 knees were enrolled. Of these, 428 patients (856 knees) underwent staggered bilateral TKA with 7 days interval in a single hospitalization [15] and 403 patients underwent unilateral TKAs. The study was approved by the institutional review board with waiver of documentation of informed consent, which allowed non-randomized retrospective review.

Patients were divided into three groups: those who were managed with chemoprophylaxis using an indirect factor Xa inhibitor (CPX group, 414 cases), those who were managed with intermittent pneumatic compression device (IPC group, 425 cases), and those who were managed without pharmacological or mechanical prophylaxis (control group, 420 cases). At the beginning, patients were randomly assigned to control group and CPX group. Thereafter consecutive similar number of patients who were managed with IPC device following TKA assigned to IPC group. The incidence of overall, proximal, symptomatic DVT and symptomatic pulmonary embolism (PE) were compared among the groups. Also, we evaluated the difference of DVT incidence between staggered bilateral TKA group (856 knees) and unilateral TKA group (403 knees).

All patients applied bilateral compression stockings immediately after the surgery. Patients in CPX group received subcutaneous doses of 2.5 mg of fondaparinux (Arixtra; GlaxoSmith-Kline, UK) once daily for 5 days [8]. The first postoperative injection was administered 6–8 hours after the surgery and the second injection was 24 hours after the first. For IPC group, portable sequential compression device (SCD Express^{TM} Compression System, Tyco Healthcare/Kendall, Mansfield, MA) was used on both legs from the immediate postoperative period whenever the patient was not weight bearing. The IPC sleeves consisted of three circumferential air chambers running the distance from the ankle to the thigh and inflated sequentially and it was continued for 6 days until the patients were discharged home.

2.2. Surgical procedure and postoperative management

All patients had a cemented TKA using conventional intramedullary femoral jig based instrumentation by a single surgeon (first author). A single suction drain was used for 24 hours and it allowed recording of postoperative blood loss. All patients received an identical postoperative pain protocol including multimodal approach and were managed with the same rehabilitation protocol [8]. They were allowed partial weight bearing ambulation using crutches from postoperative day 1 and discharged at home on postoperative day 6.

2.3. Evaluation

All patients underwent routine ultrasonography preoperatively and CTV on postoperative day 6. Clinical symptoms suggestive of DVT, including pain and swelling of the limb, calf tenderness, venous engorgement, enlargement of the girth of the calf or thigh and the Homan's sign were evaluated daily till the patient was discharged. Any shortness of breath, chest pain or blood-streaked sputum suggestive of pulmonary embolism was also looked out for. In case of suspicious symptomatic PE, it was confirmed by computed tomographic pulmonary angiography. Patients were then followed up subsequently at 6 weeks, 3 months, 6 months and 1 year postoperatively. During the follow-up, patients were instructed to report any symptoms or signs of VTE, bleeding, or any other clinical event.

Demographic characteristics including gender, age, body mass index (BMI) and tourniquet time were recorded. Serum concentration of D-dimer was measured and coagulation assay such as platelet count (PLT), prothrombin time (PT), activated partial thromboplastin time (aPTT) were performed before the operation and on postoperative day 5. Postoperative drained blood volume and hemoglobin level were recorded. Also, the patients were assessed for bleeding during hospitalization and at outpatient visits. The major bleeding was included clinically overt bleeding with requiring transfusion of two or more units of blood products (considering 450 ml of reinfused shed blood as 1 U) [8], bleeding with a serious or life-threatening clinical event or requiring surgical intervention, bleeding occurred in retroperitoneal, intracranial, or intraocular location, or bleeding resulted in death [16]. The bleeding was classified as minor if it was overt, did not meet the criteria for major bleeding, and was associated with at least one of the following features: ecchymosis larger than 5 cm at its greatest dimension around the operated knee or hemarthrosis resulted from intra-articular bleeding which required to perform arthrocentesis [17]. These minor bleeding complications were recorded during hospitalization and at outpatient visits. Also, periprosthetic joint infection or mechanical complications were recorded. All patients were assessed by two authors throughout the study periods.

2.4. Statistical analysis

Data were analyzed statistically with SPSS Statistics (version 21; SPSS). Frequency analysis was used for demographic evaluation and descriptive statistics. Statistical comparison of age, BMI, tourniquet time, pre- and postoperative D-dimer, Hb, PT and aPTT level between three groups was performed by one-way analysis of variance (ANOVA). When ANOVA revealed a significant difference, Student–Newman–Keuls (SNK) test was used for further comparison. Differences of proportion of prevalence of DVT or bleeding complications were analyzed by linear-by-linear association test and Chi^2 test. For all tests, $p < 0.05$ was considered significant.

Table 1
Patients demographics.

Information	Control group (n = 420)	CPX group (n = 414)	IPC group (n = 425)	p-value
Gender (male:female)	37:383	28:386	45:380	n.s.
Mean age (years)	69.4 ± 6.6	69.4 ± 6.8	70.1 ± 6.0	n.s.
BMI (kg/m^2)	26.7 ± 3.5	27.0 ± 4.2	26.7 ± 3.8	n.s.
Laboratory				
D-dimer (μg/mL)	1.0 ± 1.0	1.0 ± 1.0	1.1 ± 1.1	n.s.
Hb (g/dL)	12.0 ± 1.8	12.2 ± 1.7	11.8 ± 1.5	n.s.
PT (s)	13.0 ± 1.0	13.1 ± 0.9	13.0 ± 1.2	n.s.
aPTT (s)	34.9 ± 4.4	34.8 ± 3.8	34.5 ± 3.9	n.s.

BMI: body mass index; Hb: hemoglobin; PT: prothrombin time; aPTT: activated partial thromboplastin time; n.s.: non-specific.

Table 2
Incidence of DVT following TKA in 3 groups.

Event	Control group (n, %)	CPX group (n, %)	IPC group (n, %)	p-value
Overall DVT	62 (14.8%)	26 (6.3%)	48 (11.3%)	< 0.001
Proximal DVT	8 (1.9%)	3 (0.7%)	4 (0.9%)	n.s.
Symptomatic DVT	3 (0.7%)	0	3 (0.7%)	n.s.
Symptomatic PE	0	0	0	n.s.

DVT: deep vein thrombosis; PE: pulmonary embolism; n.s.: non-specific.

Table 3
Comparison of the incidence of overall DVT.

Comparison groups	% of DVT	p-value	OR (95% CI)
Control vs. IPC	14.8 vs. 11.3	0.152	0.74 (0.49–1.10)
Control vs. CPX	14.8 vs. 6.3	< 0.001	0.39 (0.24–0.63)
IPC vs. CPX	11.3 vs. 6.3	0.011	0.53 (0.32–0.87)

OR: odds ratio; CI: confidence interval; DVT: deep vein thrombosis; IPC: intermittent pneumatic compression; CPX: chemoprophylaxis.

Table 4
Incidence of DVT following TKA between staggered bilateral TKAs (856 knees) and unilateral TKAs (403 knees).

Event	Staggered bilateral TKA group (n, %)	Unilateral TKA group (n, %)	p-value
Overall DVT	87 (10.2%)	49 (12.2%)	n.s.
Proximal DVT	11 (1.3%)	4 (1.0%)	n.s.
Symptomatic DVT	4 (0.5%)	2 (0.5%)	n.s.
Symptomatic PE	0	0	n.s.

TKA: total knee arthroplasty; DVT: deep vein thrombosis; PE: pulmonary embolism; n.s.: non-specific.

3. Results

Demographic variables such as age, gender, BMI, tourniquet time and preoperative laboratory findings such as D-dimer, Hb, PT and aPTT were similar among the groups (Table 1).

Incidence of overall DVT was 14.8% in control group, 6.3% in CPX group and 11.3% in IPC group ($p < 0.001$, Table 2). CPX group showed significantly lower incidence of overall DVT than other groups ($p < 0.001$), while IPC group showed no significant difference compared to control group (Table 3). However, incidences of proximal DVT, symptomatic DVT and PE were very low in all groups and there were no significant differences among the groups (Table 2). There was no significant difference of DVT incidence between staggered bilateral TKA group and unilateral TKA group (Table 4).

There was no significant difference in postoperative laboratory findings (D-dimer, Hb, PT, aPTT) and drained blood volume among the groups (Table 5). In terms of bleeding complications, no major hemorrhages were observed in all groups while CPX group showed significantly higher incidence of ecchymosis than other two groups (Table 6).

4. Discussion

Current study showed the incidence of overall and proximal DVT without prophylaxis was 14.8% and 1.9%, which seems concurs with recent reports in Asian [18,19]. Moreover, we tried to find effectiveness of single use of IPC device in this low incidence population but the IPC device did not reduce the incidence to significant lower level. On the contrary, chemoprophylaxis could reduce overall incidence of DVT significantly.

There has been a few information regarding efficacy of mechanical prophylaxis compared to chemoprophylaxis or non-prophylaxis following TKA in Asian population [19]. One study compared the efficacy of different modes of thromboprophylaxis in Asian patients and reported relatively good effect of mechanical and pharmacological prophylaxis for overall DVT [19]. However, the study performed with some bias; small sample size with insufficient power, including computer-assisted TKA, which might affect the prevalence since it did not invade femoral intramedullary canal and including various preoperative diagnoses for TKA. Current study had sufficient sample size (more than 400 cases in each group) and included only conventional surgical technique [13,14].

It has been reported that single use of mechanical compression devices might be an appropriate thromboprophylaxis in a low incidence population [7,9,19]. However, current comparative study confirmed that single use of mechanical prophylaxis was not effective for prevention of DVT following TKA. Early ambulation increases venous blood flow and reduces venous stasis like IPC device which also focuses on reducing venous stasis and blood stagnation by promoting venous blood flow through external compression [20]. Since all patients were managed with early mobilization protocol which included range of motion, quadriceps and calf pump exercises on postoperative day 0 and were allowed partial weight bearing on day 1, it might reduce the prevalence of DVT and make a negligible effect of mechanical compression methods [21,22]. Therefore, IPC device, which is steadily attractive to many surgeons, did not prove its previous promising results [7].

Safety analysis showed significant increase in the incidence of ecchymosis in chemoprophylaxis group though there was no fatal or major bleeding, which was concordant with previous literature (Table 6) [8]. With the exception of ecchymosis, another Asian study demonstrated the safety evaluation after TKA and there was no difference in bleeding events such as major bleeding or hemarthrosis [23]. The results are similar to our study (control group 4.8%, CPX group 6.3%, IPC group 3.8%).

In spite of informative results, this study has some limitations. Firstly, this study was a retrospective, non-randomized review. However, we prospectively performed DVT protocol using a critical pathway and recorded all the data but reviewed retrospectively. Moreover, it seemed practically and ethically difficult to make a prospective design for these 3 different ways to apply in same time for the study. Secondly, the sample size of current study might be relatively small to compare the proximal DVT or symptomatic PE. However, our primary outcome parameter was the overall incidence of DVT like most literatures and then evaluated other incidences as secondary outcomes. In addition, based on our extremely low incidence of proximal DVT and PE, it would be difficult to collect enough sample size required more than thousands of consecutive cases in a single institute. Thirdly, female predominance and a low incidence, Asian cohort enrolled in current study. In contrast to Western population, Korean female has a 3, 4-fold higher use in TKA [24]. Moreover, comparing the result with Western population would be interesting in the near future. Fourthly,

Table 5
Perioperative outcomes of the 3 groups.

Information	Control group	CPX group	IPC group	*p*-value
Tourniquet time (min)	77 ± 18	75 ± 18	76 ± 14	n.s.
Drained blood volume (cm^3) (24 hours)	249 ± 183	255 ± 200	241 ± 163	n.s.
D-dimer (μg/mL)	2.7 ± 2.1	2.6 ± 1.8	2.4 ± 1.8	n.s.
Hb (g/dL)				
Postop 1 day	10.0 ± 1.3	10.2 ± 1.3	10.0 ± 1.3	n.s.
Postop 2 day	9.3 ± 1.2	9.2 ± 1.2	9.4 ± 1.2	n.s.
PT (s)	14.2 ± 1.4	14.2 ± 1.1	13.9 ± 1.6	n.s.
aPTT (s)	35.8 ± 4.6	36.4 ± 5.0	35.1 ± 5.4	n.s.

CPX: chemoprophylaxis; IPC: intermittent pneumatic compression; Hb: hemoglobin; PT: prothrombin time; aPTT: activated partial thromboplastin time; n.s.: non-specific.

Table 6
Complication rates of the 3 groups.

	Control group(*n*, %)	CPX group(*n*, %)	IPC group(*n*, %)	*p*-value
Major bleeding complications[a]	0	0	0	n.s.
Minor bleeding complications				
Ecchymosis	202 (48.1%)	275 (66.4%)	221 (52.0%)	< 0.001[b]
Hemarthrosis	20 (4.8%)	26 (6.3%)	16 (3.8%)	n.s.
Acute periprosthetic joint infection	0	1 (0.2%)	0	n.s.

CPX: chemoprophylaxis; IPC: intermittent pneumatic compression; n.s.: non-specific.

[a] A major bleeding complications were defined by major hemorrhage occurring in any of the following sites: intracranial, intraocular, epidural, or retroperitoneal.

[b] $p < 0.001$ for statistical analysis between CPX and control group; $p < 0.001$ for statistical analysis between CPX and IPC group; no significant difference between control group and IPC group.

current research that only included Asian population may be debate to Western population with relatively higher incidence of DVT following TKA. Comparative research with large cohort would be necessary.

Despite these limitations, the authors emphasize that this is an informative study reporting a single surgeon series assessing the efficacy of IPC device and comparing it with chemoprophylaxis and non-prophylaxis and will be of clinical relevance to prevent VTE following TKA in a low incidence population.

5. Conclusion

Current study confirmed that prevalence of VTE following TKA is still low in Asian population. Use of IPC device could not reach significant level of DVT prophylaxis compared to control group and only chemoprophylaxis showed significantly reduce the incidence of overall DVT. Single use of IPC device does not show effective thromboprophylaxis in a low DVT incidence population.

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Contribution

Kang-Il Kim: conception and design, data analysis and interpretation, and final approval of manuscript.

Dong-Kyoon Kim: collection and/or assembly of data, data analysis and interpretation, and manuscript writing.

Sang-Jun Song and Se-Jung Hong: collection and/or assembly of data.

Dae-Kyung Bae: conception, data analysis and interpretation.

Disclosure of interest

The authors declare that they have no competing interest.

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