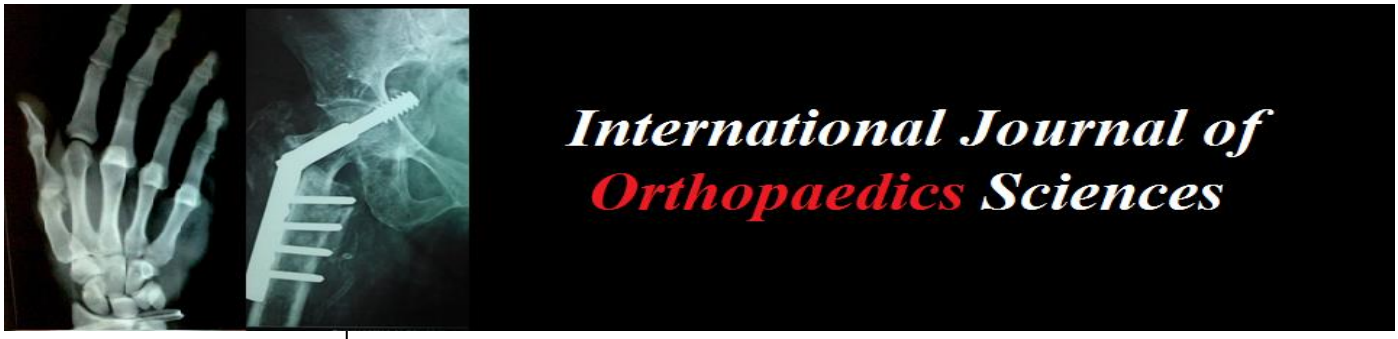

E-ISSN: 2395-1958
P-ISSN: 2706-6630
IJOS 2020; 6(2): 933-940

www.orthopaper.com
Received: 23-01-2020
Accepted: 24-02-2020

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Review of safety of single stage bilateral total knee replacement with cruciate retaining prosthesis and subvastus approach

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DOI: https://doi.org/10.22271/ortho.2020.v6.i2o.2164

Abstract
Background: With Most patients with Osteoarthritis needing bilateral TKR for optimal functional results, the debate on whether to do a single stage bilateral TKR or staged bilateral TKR has become common. The aim of this study was to review the safety of single stage bilateral TKR done in our institution.
Materials and Methods: We did a retrospective review of 127 cases of single stage bilateral TKR that was done in our institution during a period of 38 months from 2015 to 2018.Electronic medical Records of patients who underwent single stage Bilateral TKR during this period were reviewed. Only patients who received cruciate retaining prosthesis and had subvastus approach were included. Results were analysed using Chi square testing in terms of ASA grade and age and incidence of complications.
Results: ASA grade and age was seen to be correlating with incidence of complications during the intraoperative and immediate postoperative period. The incidence of complications was 42.9% in the ASA-III group with p value less than 0.00001. The Incidence of complications was 16 % in the above 70 years age group with P value less than 0.00982. In the ASA-III group, the incidence was 50% in the above 70 group when compared to the 60-70 group (40%) with P value of less than 0.00001.
Conclusions: Judicious patient selection using ASA grade and age may minimise complications of single stage bilateral TKR. The use of Cruciate retaining prosthesis and subvastus approach may have contributed to the low incidence of complications.

Keywords: Safety of bilateral TKR, ASA grading in TKR, subvastus approach

Introduction
Total knee replacement surgeries have increasingly become a common procedure in the last decade or so. Most of these patients are affected bilaterally and require both knee total knee replacement for full functional recovery [3]. Though, there have been multiple studies on the subject, there is no actual consensus on whether to do a single stage bilateral total knee replacement (SSBTR) or a staged bilateral total knee replacement (SBTKR). This debate has gained momentum within the last few years, with increasing medicolegal implications. The advantages of SSBTR has been outlined to be the need for only a single surgery, single anaesthesia, simultaneous and symmetrical rehabilitation of both knees and cost effectiveness. On the other hand the disadvantages are mainly increased morbidity due to cardiopulmonary insult, need for transfusions, incidence of DVT and Pulmonary Embolism [1, 2, 3, 17, 18, 19, 20].
The aim of this study was to do a retrospective review of the complications during the intraoperative and immediate postoperative period in cases of SSBTR done in our institution.

Materials and Methods
This was a retrospective study involving 127 cases of SSBTR done in our institution during a period of 38 months ranging from 2015 to 2018.Electronic medical records (EMR) were collected for these cases. Majority of cases had subvastus approach and received cruciate retaining prosthesis, and hence, for the purpose of standardisation, only these cases were included in the study. Records which were incomplete or having inconsistent data were excluded.

The surgeries were conducted by author 1 and author 3.Author 1 has 15 years of experience in arthroplasty and author 3 has 35 years of experience in arthroplasty. All patients had undergone standard preoperative anaesthesia checkup and anaesthetic orders were followed. Preoperative ASA grading during anaesthesia checkup noted in the EMR was recorded as the indicator of preoperative health status. Age and ASA grade were used as determinants. Prophylactic antibiotics; Cefuroxime 1.5 gm was administered 30 minutes prior to incision. Combined spinal and epidural anaesthesia was generally used in all cases unless there was a contraindication noted by the anaesthetist. All patients were operated through subvastus approach. Tourniquet was used in all cases. Tranexamic acid was administered prior to incision and also prior to deflation of tourniquet in each knee. All these patients got Cruciate retaining prosthesis. The operating time was estimated from the total tourniquet time with deduction of 10 minutes, which was the average overlap time during which wound closure was done in the first operated knee and simultaneous exposure of the other knee happens. Drains were used in all cases. All our patients are monitored in the postoperative unit after surgery and shifted out on the first postoperative day. ICU admission is done only when there is any indication for the same, as decided by the anaesthetist during surgery or during the stay in the postoperative unit. Postoperative DVT prophylaxis including Low molecular weight heparin and DVT pump was used as a standard protocol. Patients were mobilised on the second postoperative day to full weight bearing with walker frame, quadriceps strengthening and range of motion exercises. They were discharged once wound was dry and Knee ROM of minimum 90 degrees was achieved on the 6th day of surgery.

Preoperative ASA grading done by the anaesthetist was used as a tool for determining the preoperative health status of the patients. The ASA score is a subjective assessment of a patient's overall health that is graded on five classes (I to V) [5]. The study group was divided into three age groups, with group I being less than 60, group II being 60-69 and group III being 70 years and above. The incidence of intraoperative or immediate postoperative complications were analysed with respect to these determinants. Based on previous studies, the complications looked for were need for transfusions, deep vein thrombosis, Pulmonary embolism and cardiovascular complications [1, 2, 3, 17, 18, 19, 20].

In addition, we also looked into the incidence of other factors such as need for ICU stay, infection, electrolyte imbalances, acid base disorders, extended hospital stay and mortality.

Statistical significance for the findings was assessed through Chi square tests with P value significance being less than .05

Results

A total of 127 cases (254 knees) were included in the study. 86.61% of these cases were females and 13.38% were males. [Tab.1] Majority of our patients belonged to the 60-69 age group with the mean age being 64.20. [Tab 1]

89.7% of the total patients belonged to ASA-II category. Only 5.5% of the patients belonged to ASA-III category. No patients belonging to ASA-IV or higher underwent SSBTR. 4.7 % of the patients were ASA-I. [Tab 1] Around 49% of the patients had hypertension and 38 % of the patients were diabetic. Cardiac diseases were documented in around 5.4% of the patients. Patients in ASA-III grade were seen to have cardiac illness as the major comorbidity.

Average operating time was 170 minutes. Intraoperative blood loss was found to be 500-700 ml. Out of the 127 patients undergoing SSBTR, 38 patients (29.9%) required postoperative transfusions. [Fig 1] None of the patients had intraoperative complications 6 patients (4.72%) of the total developed complications requiring ICU stay in the postoperative period. [Fig 1]

A 71 year old female patient who was ASA-III category, developed supraventricular tachycardia, 3 weeks post SSBTR, which was reverted with Valsalva manoeuvre and recovered with subsequent admission to CCU and conservative management.

74 year old Female patient (ASA-II) developed hypotension in the post operative, which was corrected with transfusions.

75 year old male patient (ASA-II) developed hyponatraemia on the 4th postoperative day but recovered subsequently with corrective measures.

76 year old Female patient who was an ASA-II category patient developed disorientation and restlessness in the postoperative period and was diagnosed to have lactic acidosis. Patient was admitted to the ICU and NIV initiated along with sodium bicarbonate therapy and went on to achieve full recovery.

69 year old male patient (ASA-III) developed Supraventricular Tachycardia in the immediate postoperative period and required ICU admission. He recovered with rate controlling measures.

65 year old female patient was found to have respiratory alkalosis and low oxygen saturation in the post operative period. She recovered fully with corrective measures. She belonged to ASA-III category.

There was one case of superficial wound infection which settled with intravenous antibiotics. No cases of deep infections were seen. No cases of clinical DVT or pulmonary embolism was seen. Average hospital stay was 6 days.

There were no complications requiring ICU stay in the ASA-I group. The incidence of complications was 2.6% in the ASA-II group and 42.9% in the ASA-III group (Fig-2, Tab-2). Chi Square testing showed p value to be less than 0.00001(Tab 3)

The less than 60 years group had no complications. 3.0% of the patients in the 60-69 age group developed complications. (Fig 3, Tab-3) The Incidence of complications was 16 % in the above 70 years age group. P value was found to be less than 0.00982.

In grade II patients, there were no complications in the less than 60 or 60-70 age groups. While incidence of complications was 13% in the above 70 age group. In the ASA-III group, the incidence was 50% in the above 70 group when compared to the 60-70 group (40%) (Fig-4, Tab-4). Chi Square tests for the same showed a P value of less than 0.00001.

Demographics for study group

Table 1.

Age Category	Asa Grading			
	I	II	III	Total
Less Than 60	4 11.4%	31 88.6%	0 0%	35
60-69	2 3.0%	60 89.6%	5 7.5%	67
70 And Above	0 0%	23 92%	2 8%	25
Total	6 4.7%	114 89.8%	7 5.5%	127

Age Category	Sex Distribution		
	Male	Female	Total
Less Than 60	3 8.5%	32 91.4%	35
60-69	8 11.9%	59 88.06%	67
70 and Above	6 24%	19 76%	25
Total	17 13.4%	110 86.6%	127

Asa Grading	Sex Distribution		
	Male	Female	Total
ASA-I	0 0%	6 100%	6
ASA-II	15 13.15%	99 86.8%	114
ASA-III	2 28.5%	5 71.4%	7
Total	17 13.4%	11O 86.6%	127

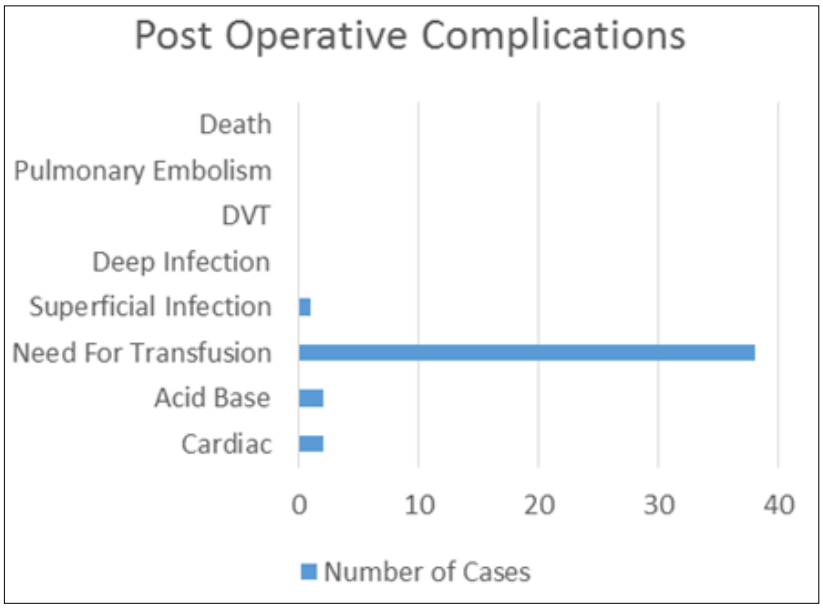

Fig 1.

Table 2.

ASA_grade * ICU_Stayed Crosstabulation

			ICU_Stayed		
			0	1	Total
ASA_grade	1	Count	6	0	6
		% within ASA_grade	100.0%	0.0%	100.0%
	2	Count	111	3	114
		% within ASA_grade	97.4%	2.6%	100.0%
	3	Count	4	3	7
		% within ASA_grade	57.1%	42.9%	100.0%
Total		Count	121	6	127
		% within ASA_grade	95.3%	4.7%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	24.020[a]	2	.000
Likelihood Ratio	11.035	2	.004
Linear-by-Linear Association	14.792	1	.000
N of Valid Cases	127		

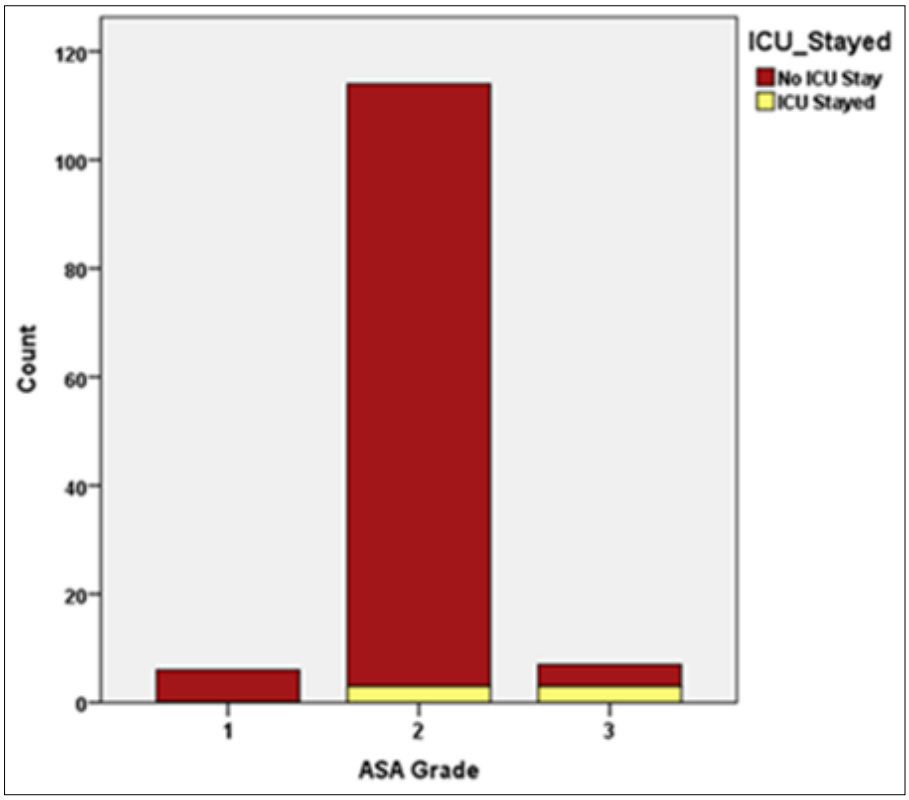

Fig 2.

Table 3.

Age Cat * ICU_Stayed

Crosstab

			ICU_Stayed		Total
			0	1	
Age Cat	Less than 60	Count	35	0	35
		% within Age Cat	100.0%	0.0%	100.0%
	60 to 69.99	Count	65	2	67
		% within Age Cat	97.0%	3.0%	100.0%
	70 and above	Count	21	4	25
		% within Age Cat	84.0%	16.0%	100.0%
Total		Count	121	6	127
		% within Age Cat	95.3%	4.7%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	9.247[a]	2	.010
Likelihood Ratio	8.372	2	.015
Linear-by-Linear Association	7.446	1	.006
N of Valid Cases	127		

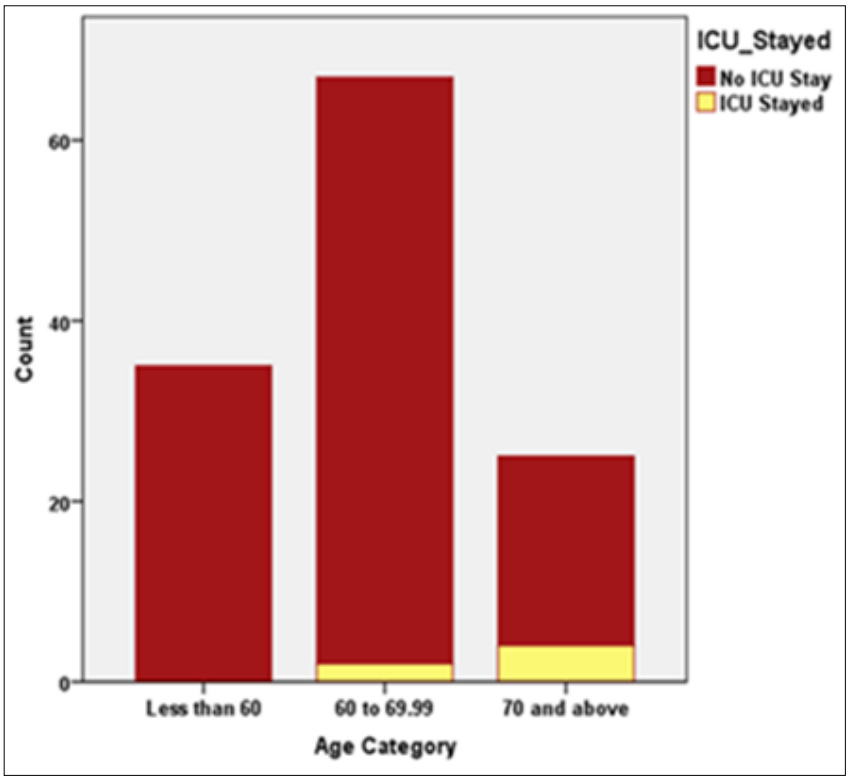

Fig 3.

Table 4.

Grad_ageCat * ICU_Stayed Crosstabulation

			ICU_Stayed		Total
			0	1	
Grad_ageCat	Grade1Age<60	Count	4	0	4
		% within Grad_ageCat	100.0%	0.0%	100.0%
	Grade1 Age60 70	Count	2	0	2
		% within Grad_ageCat	100.0%	0.0%	100.0%
	Grade2Age<60	Count	31	0	31
		% within Grad_ageCat	100.0%	0.0%	100.0%
	Grade2Age60-70	Count	60	0	60
		% within Grad_ageCat	100.0%	0.0%	100.0%
	Grade2Age>70	Count	20	3	23
		% within Grad_ageCat	87.0%	13.0%	100.0%
	Grade3Age60-70	Count	3	2	5
		% within Grad_ageCat	60.0%	40.0%	100.0%
	Grade3Age>70	Count	1	1	2
		% within Grad_ageCat	50.0%	50.0%	100.0%
Total		Count	121	6	127
		% within Grad_ageCat	95.3%	4.7%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	31.277[a]	6	.000
Likelihood Ratio	21.027	6	.002
Linear-by-Linear Association	18.423	1	.000
N of Valid Cases	127		

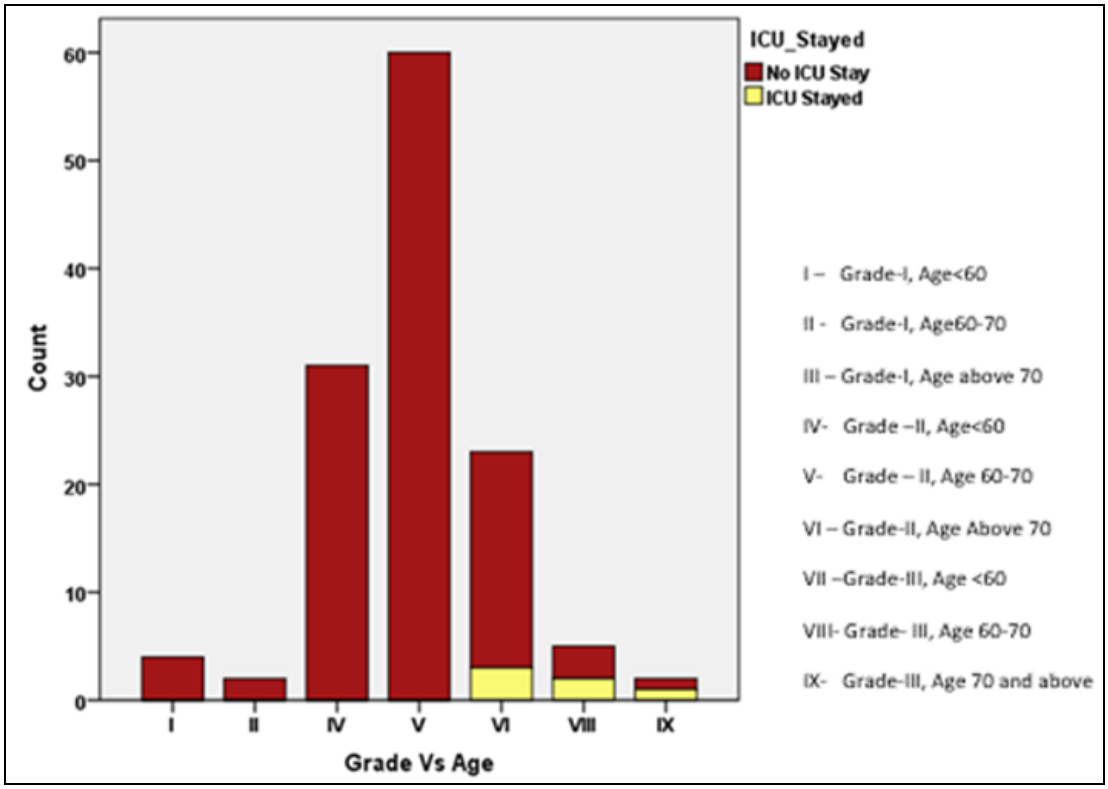

Fig 4.

Discussion

The need to review the complications of SSBTR arises during review of literature on SSBTR outcomes. Most of the studies compare SSBTR with SBTKR and the results have not led to a consensus. Almost all studies have observed increased morbidity with a bilateral procedure [1, 17, 18, 19, 20] Again, the comparison of these two procedures may not be appropriate. This study aimed to review the complications associated with single stage procedures with the objective to try and draw conclusions on whether it can be regularly recommended.

The need for only a single anaesthesia and single surgery has always been the main advantage of SSBTR, while prolonged operating time and blood loss leading to increased morbidity has been the disadvantages [1, 2, 3, 4]. Preoperative evaluation is paramount in selection of patients for SSBTR. Anaesthetists make use of ASA grading as a reliable tool for grading of patients during preanaesthetic checkup. The ASA score is a subjective assessment of a patient's overall health that is based on five classes (I to V) [5].

i) Patient is a completely healthy fit patient.
ii) Patient has mild systemic disease.
iii) Patient has severe systemic disease that is not incapacitating.
iv) Patient has incapacitating disease that is a constant threat to life.
v) A moribund patient who is not expected to live 24 hour with or without surgery.
vi) Emergency surgery, E is placed after the Roman numeral.

C Trojani [2] *et al*. did a 24-month prospective pilot study in a continuous series of 30 patients belonging to ASA I and ASA II groups and concluded that bilateral total knee replacement in a one-stage surgical procedure is a reliable alternative to a two-stage procedure in ASA 1 and 2 patients. In 2011, Memtsoudis [21] analyzed 206,573 cases of bilateral TKR and concluded that elderly patients and those with ASA-III and IV are prone to complications and SSBTR is contraindicated in this group. In our study, there were no complications requiring ICU stay in the ASA-I group. The incidence of complications was 2.6% in the ASA-II group and 42.9% in the ASA-III group (Fig-2, Tab-2). Chi Square testing showed p value to be less than 0.00001 (Tab 3), indicating a statistically significant association between ASA grade and complications (Tab-2). It would be logical to say that SSBTR is a relatively safe procedure in ASA-I, ASA-II grade patients. Our study findings were found to be correlating with previous studies in this regard [1, 2, 21].

Increasing age and incidence of perioperative complications were also assessed. The less than 60 years group had no complications. 3.0% of the patients in the 60-69 age group developed complications. (Fig 3, Tab-3) The Incidence of complications showed a rise to 16 % in the above 70 years age group. P value was found to be less than 0.00982 which shows significant statistical association between increased age and complications in patients undergoing SSBTR. (Tab-3).This again was a similar inference to previous studies [1, 2, 21].

Previous studies suggest that patients belonging to ASA-II or less are ideal candidates for SSBTR [1, 2]. Our study was also found to be leaning towards the same conclusion. We also assessed the incidence of complications with cross tabulation of both ASA grade and age with complications. In grade II patients, there were no complications in the less than 60 or 60-70 age groups. But, incidence of complications rose to 13% in the above 70 age group. In the ASA-III group, the incidence increased to 50% in the above 70 group when compared to the 60-70 group (40%) (Fig-4, Tab-4), Chi Square tests for the same showed a P value of less than 0.00001, showing statistical significance (Tab-4). Therefore, even in ASA-II grade patients, increasing age could be a red flag while planning SSBTR.

We have adopted subvastus approach as a standard for all our total knee replacement surgeries unless indicated otherwise. This choice was based on the experience of our surgeons and

also multiple studies which has documented the advantages of the approach [7, 8, 9, 10]. Subvastus approach involves a steep learning curve and may lead to prolonging of operating time at the hands of inexperienced surgeons [7, 8, 9, 10]. We did not experience significant prolongation of operating time. Optimising operating time is vital in reducing incidence of postoperative surgical wound infection [6]. Average operating time in our institute was around 170 minutes. Tourniquet was routinely used in our cases and it has been seen to reduce the total operating time by providing a clear bloodless field [11, 12]. One of the most important points against SSBTR is increased blood loss and need for postoperative transfusions[3].Blood loss can also aggravate incidence of cardiopulmonary complications adding to morbidity in cases of SSBTR. Therefore, the importance of measures to reduce blood loss finds emphasis in SSBTR. Use of tranexamic acid to reduce blood loss during TKR has been extensively studied and multiple regimen have been described [13, 14]. However, there is no clear consensus on the best protocol. We administer tranexamic acid before incision and also before release of tourniquet in each knee. Further, subvastus approach, is associated with reduced blood loss [7, 8, 9, 10]. It preserves quadriceps mechanism and post-operative quadriceps function. Conservation of patellar blood supply also leads to improved patellar function [10].

Cruciate retaining prosthesis is associated with reduced operating time [15, 16] and has been observed to have similar blood loss to posterior stabilised implants [15, 16].

Subvastus approach and use of cruciate retaining prosthesis could have been factors contributing to the low complications in our study group, but this cant be a conclusive statement as the evidence for the same is low.

Findings in literature attributes higher risk of DVT and pulmonary embolism in SSBTR [3]. In our study group, we did not have any cases of deep infections, DVT or Pulmonary embolism.

Our study seems to indicate that SSBTR can be a relatively safe procedure in patients belonging to ASA-I or ASA-II grade. An ASA grade of more than II would warrant significant caution when proceeding with SSBTR. Additionally, Even in ASA-II patients, increasing age would demand a more judicious approach to patient selection and post-operative care. Therefore, it's important that ASA grading and age be seen as factors to be weighed on a scale and surgical decisions made depending on favourability of both factors. Further, emphasis on the use of meticulous techniques to reduce intraoperative blood loss and operating time reduces the incidence of mortality and morbidity associated with the procedure. Subvastus approach and cruciate retaining prosthesis may have been contributing factors to minimise the complications, though it still would depend on the experience of the surgeons, and would also require prospective evaluation and a control group to further evaluate advantages.

Our study has several limitations. The reliance on documentation and the absence of a control group to compare with staged bilateral TKR is a major limitation. Also, the absence of a control group to compare the influence of cruciate retaining prosthesis and subvastus approach with other components and approaches limits the conclusiveness of the study.

Conclusions

Judicious patient selection using ASA grade and age can minimise the potential complications of SSBTR. The use of cruciate retaining prosthesis and subvastus approach, may have indirectly influenced the incidence of low complications.

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