CLINICAL STUDY

Safety and Outcomes of Transradial Access in Patients with International Normalized Ratio 1.5 or above

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ABSTRACT

Purpose: To examine the safety and outcomes for patients undergoing transradial noncoronary interventions with international normalized ratio (INR) ≥1.5.

Materials and Methods: A retrospective review of 2,271 transradial access (TRA) cases performed from July 2012 to July 2016 was conducted. Criteria for inclusion were moderate bleeding risk cases with preprocedure INR ≥1.5. Within the study period, there were 176 moderate bleeding risk procedures (transarterial chemoembolization: 70/176 [39.8%]; Barbeau B: 121/176 [68.8%]; 5-F sheath: 157/176 [89.2%]) performed on 122 patients (age 61.6 ± 12.1 years, 68.9% male, body mass index 28.0 kg/m^2) with INR ≥1.5.

Results: Technical success was achieved in 98.9% of cases. Grade 1/2 hematomas developed in 10 cases (5.7%). Age ≥65 years (P = .042) and female sex (P = .046) were predictive of access site bleeding complications. Fresh frozen plasma (FFP) transfusion was administered in 11.4% of cases (n = 20). Baseline INR and creatinine were significantly different between transfused and nontransfused cases (P values .006 and .028, respectively). Minor access site bleeding occurred in 3/20 cases (15%) receiving prior FFP transfusion and 7/156 nontransfused cases (4.5%), with no significant difference between these 2 groups (P = .072).

Conclusions: TRA in patients with elevated INR appears to be safe in our experience. Age ≥65 years and female sex were associated with increased incidence of access site bleeding. Although INR correction was not standardized in this cohort, preprocedure FFP transfusion did not decrease bleeding complications.

ABBREVIATIONS

FFP = fresh frozen plasma, INR = international normalized ratio, TFA = transfemoral access, TRA = transradial access

Transradial access (TRA) has been shown to be a safe and feasible alternative to transfemoral access (TFA) for both percutaneous coronary and noncoronary arterial interventions. Past work, including multicenter prospective studies, concerning the use of TRA in coronary interventions has demonstrated decreased access site complications, decreased need for postprocedure transfusion, and improved mortality (1–4).

The Society of Interventional Radiology and Cardiovascular and Interventional Radiology Society of Europe (SIR/CIRSE) consensus guideline for coagulopathy management suggests correcting international normalized ratio (INR) to <1.5 for all moderate bleeding risk cases. These include all arterial interventions with access size to 7F, chemoembolization, uterine fibroid embolization, and certain others (5). Studies evaluating the relationship between TRA

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Table 1. Patient Demographics

Age (y)	61.6 ± 12.1
BMI (kg/m^2)	28.0 ± 5.6
Sex	
Male	84 (68.9%)
Female	38 (31.1%)
Ethnicity	
White	51 (41.8%)
Hispanic	26 (21.3%)
Black	20 (16.4%)
Asian	7 (5.7%)
Unknown/other	18 (14.8%)

Note–Values are presented as mean ± SD or n (%).
BMI = body mass index.

in noncoronary interventions and bleeding complications have been rare. TRA was recently shown to be safe in patients with thrombocytopenia, potentially without requiring platelet transfusion (6). Although the benefits of TRA demonstrated in coronary interventions—particularly decreased transfusion rates and lower incidence of bleeding complications—might reasonably be expected to translate to noncoronary interventions, it was important to explore this question directly, because patients coagulopathic due to renal disease and hepatic dysfunction frequently undergo noncoronary interventions. The present study examined safety and outcomes in patients undergoing noncoronary interventions with INR ≥1.5, the threshold for correction in moderate bleeding risk cases according to SIR/CIRSE guidelines.

METHODS

The local Institutional Review Board approved this single-center retrospective study. A review of a prospectively maintained database was conducted for the period of July 2012 to July 2016. Data were obtained through the EPIC electronic medical record system (EPIC, Verona, Wisconsin). Patients included in the study underwent moderate bleeding risk procedures according to SIR/CIRSE guidelines with preprocedure INR ≥1.5 (5). One patient was found to have Barbeau D waveform before access was obtained, and the case was completed with TFA only; that patient was excluded from analysis.

From July 2012 to July 2016, a total of 2,271 TRA cases were completed. Of these, 176 moderate-bleeding-risk TRA access cases were performed on 122 individual patients with preprocedure INR ≥1.5. Patient demographics are listed in Table 1.

The majority of procedures were interventional oncology procedures, including transarterial chemoembolization (n = 70; 39.8%), radioembolization (RE) (n = 28; 15.9%), and RE mapping studies (n = 46; 26.1%). Several additional procedures were performed, including splenic artery embolization (n = 4; 2.3%), bland hepatic embolization (n = 2; 1.1%), transplant renal artery stent placement (n = 2; 1.1%), common femoral artery stent placement (n = 1; 0.6%), superior mesenteric artery stent placement (n = 1; 0.6%), and uterine fibroid embolization (n = 1; 0.6%). Twenty-one cases were emergency interventions, including hemorrhage embolizations (n = 20; 11.4%) and an occluded transplant hepatic artery intervention (n = 1; 0.6%). More detailed procedure characteristics are provided in Table 2. Etiologies for INR elevation in each case are listed in Table 3.

Evaluated outcomes included technical success, bleeding complications, access site complications, postprocedure blood product transfusion requirements, neurologic complications, and 30-day mortalities. Technical success was

Table 2. Procedure Characteristics, n (%)

Procedure type	
Transarterial chemoembolization	70 (39.8%)
RE mapping	46 (26.1%)
RE	28 (15.9%)
Other visceral interventions	32 (18.2%)
Barbeau test	
A	35 (19.9%)
B	121 (68.8%)
C	16 (9.1%)
N/A	4 (2.3%)
Sheath size	
4 F	2 (1.1%)
5 F	157 (89.2%)
6 F	17 (9.7%)
Catheter	
5-F Sarah	139 (79.0%)
6-F MPA	5 (2.8%)
6-F JR	5 (2.8%)
4-F Tempo Aqua	5 (2.8%)
5-F Sherpa	4 (2.3%)
5-F Cobra	3 (1.7%)
Other	15 (8.5%)

N/A = not available; RE = radioembolization.

Table 3. Etiology of INR Elevation, n (%)

Cause of elevated INR	
Liver disease with HCC	149 (84.7%)
Anticoagulation	12 (6.8%)
Liver disease without HCC	9 (5.1%)
DIC	3 (1.7%)
Other	3 (1.7%)
Cause of elevated INR in transfused cases	
Liver disease	11 (55%)
Anticoagulation	7 (35%)
DIC	2 (10%)

DIC = disseminated intravascular coagulation; HCC = hepatocellular carcinoma; INR = international normalized ratio.