Research Article

The Rise of Transradial Artery Access for Percutaneous Coronary Intervention in Patients with Acute Coronary Syndromes in Australia

Ryan James Ocsan,1 Ata Doost,1,2 Paul Marley,3 and Ahmad Farshid1,3

1College of Health and Medicine, The Australian National University, Canberra, ACT, Australia
2Department of Cardiology, Fiona Stanley Hospital, Murdoch, WA, Australia
3Department of Cardiology, The Canberra Hospital, Canberra, ACT, Australia

Correspondence should be addressed to Ryan James Ocsan: ryan.ocsan@gmail.com

Received 6 July 2020; Revised 6 November 2020; Accepted 11 November 2020; Published 29 November 2020

Academic Editor: Stefano Rigatti

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Objectives. The aim of this study was to evaluate the outcomes of acute coronary syndrome (ACS) patients undergoing percutaneous coronary intervention (PCI) via transradial artery access (TRA) or transfemoral artery access (TFA). Background. Over the last decade, evidence for the benefit of TRA for PCI has grown, leading to a steady uptake of TRA around the world. Despite this, the topic remains controversial with contrary evidence to suggest no significant benefit over TFA. Methods. A retrospective study of consecutive ACS patients from 2011 to 2017 who underwent PCI via TRA or TFA. The primary outcome was Major Adverse Cardiovascular Events (MACE), a composite of death, myocardial infarction (MI), target lesion revascularisation (TLR), or coronary artery bypass graft surgery (CABG) at 12 months. Secondary outcomes included Bleeding Academic Research Consortium (BARC) bleeding events scored 2 or higher, haematoma formation, and stent thrombosis, in addition to all individual components of MACE. Results. We treated 3624 patients (77% male), with PCI via TFA (n = 2391) or TRA (n = 1233). Transradial artery access was associated with a reduction in mortality (3% vs 6.3%; p < 0.0001), MI (1.8% vs 3.9%; p = 0.0004), CABG (0.6% vs 1.5%; p = 0.0205), TLR (1% vs 2.9%; p < 0.0001), large haematoma (0.4% vs 1.8%; p = 0.0003), BARC 2 (0.2% vs 1.1%; p = 0.0029), and BARC 3 events (0.4% vs 1.0%; p = 0.0426). On multivariate Cox regression analysis, TFA, age ≥ 75, prior PCI, use of bare metal stents, cardiogenic shock, cardiac arrest, and multivessel coronary artery disease were associated with an increased risk of MACE. Conclusion. Despite the limitations secondary to the observational nature of our study and multiple confounders, our results are in line with results of major trials and, as such, we feel that our results support the use of TRA as the preferred access site in patients undergoing PCI for ACS to improve patient outcomes.

1. Introduction

Percutaneous coronary intervention (PCI) remains the definitive treatment for patients with acute coronary syndromes (ACS) [1]. In this setting, PCI is associated with both ischaemic and bleeding complications and the risk of haemorrhage from the arterial access site is amplified by concurrent administration of antiplatelet and anticoagulant drugs. Both major and minor bleeding events post-PCI are associated with worse outcomes, as they may trigger significant haemodynamic alterations, a need for blood transfusion, or an early cessation of antiplatelet therapy, which are all associated with increased cardiovascular events and mortality [2, 3]. There are multiple risk factors for post-PCI bleeding [4], including arterial access site. The radial artery is smaller and more superficial than the femoral artery, making haemostatic management more predictable. Caveats to transradial artery access (TRA) include the initial operator learning curve and experience [5, 6], age-related decline in vessel integrity [7], higher fluoroscopy times and thus, higher radiation exposure compared to transfemoral artery access.
and uncommon radial-specific complications such as radial artery occlusion or perforation [9, 10]. The MATRIX trial of TRA versus TFA in ACS demonstrated a significant reduction in Major Adverse Cardiovascular Events (MACE) and bleeding with TRA [11], whereas the RIVAL trial did not show a difference in MACE or major bleeding events [12].

Hence, the role of arterial access choice in the reduction of MACE remains controversial. On balance, TRA has been increasingly found to be beneficial in improving outcomes particularly in high-risk groups (e.g., elderly, females, extremes of body mass index (BMI), and significant comorbidities) [7, 10, 13, 14]. Preference for TRA dominates in the United Kingdom and New Zealand [15], but adoption in the United States (US) [16] and Australia (with significant interstate variation) [15] has been slower, yet steadily increasing.

The results of randomised control trials (RCT) may not reflect the situation in real-world populations due to stringent selection criteria, under-representation of high-risk groups, exclusive study populations of either ST-segment elevation myocardial infarction (STEMI) [17, 18], or non-ST-segment elevation myocardial infarction (NSTEMI) [19, 20] and variable definitions of recordable bleeding events [11, 15, 17, 19, 21]. Our aim was to document the dramatic trend in adoption of TRA at our institution and determine if there were any differences in the occurrence of MACE and bleeding events using TRA or TFA in consecutive ACS patients undergoing PCI.

2. Materials and Methods

2.1. Study Setting. A retrospective analysis was conducted of the PCI registry at our tertiary referral centre that serves a population of approximately 700,000. Percutaneous coronary intervention is provided 24 hours a day for the management of STEMI patients and on-site cardiothoracic surgery is available. In addition to patients presenting with ACS to our Emergency Department, patients were also transferred urgently or semiurgently from several non-PCI centres ranging in distance from 15 to 200 km.

The analysis was conducted on patients admitted between January 2011 and December 2017 with a 12-month follow-up. The study was approved by the Research Ethics Committee as an ongoing clinical audit. All patients with ACS who subsequently underwent PCI were included. Diagnosis was made based on clinical presentation, electrocardiogram findings and cardiac biomarkers. Patients with stable angina and patients who died before the start of the procedure were excluded from this study.

The interventional procedure was conducted according to standard techniques. Patients were treated with aspirin (300 mg) and a P2Y<sub>12</sub> receptor inhibitor (clopidogrel, prasugrel, or ticagrelor) prior to arrival at the catheterisation laboratory except in STEMI patients who were treated at the catheterisation laboratory. New P2Y<sub>12</sub> inhibitors (prasugrel/ticagrelor) were available for use at our institution since 2011. Unfractionated heparin was given at the catheterisation laboratory and bivalirudin was not used. Percutaneous coronary intervention was performed by one of six operators via TRA or TFA at the operator’s discretion. The TRA program at our institution began in 2012. Vascular closure devices (VCD) were used with TFA when clinically feasible, and TRA haemostasis was achieved using the TR Band (Terumo Corporation).

Patients’ demographics, procedure details, and in-hospital complications were prospectively collected by research officers and entered into the PCI registry. Follow-up was carried out routinely at 12 months by letter, phone call, contact with the patients’ primary doctor, and review of medical records, as previously described [22].

2.2. Definitions and Outcomes. Acute coronary syndrome was diagnosed as per the 4<sup>th</sup> Universal Definition of Myocardial Infarction [23]. The primary outcome was MACE (a composite of death, myocardial infarction (MI), target lesion revascularisation (TLR), or coronary artery bypass graft surgery (CABG)) at 12 months. Target lesion revascularisation is defined as any repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other target lesion-related complications. Secondary outcomes included Bleeding Academic Research Consortium (BARC) bleeding events which scored 2 or higher [24], haematoma formation, and stent thrombosis, in addition to all individual components of MACE. Haematoma was defined as a swelling secondary to subcutaneous bleeding requiring medical intervention (i.e., BARC bleeding type 2). Stent thrombosis was defined as definite stent thrombosis according to the Academic Research Consortium criteria [24].

2.3. Statistical Analysis. Data were reported as numbers and percentages for categorical variables and means and standard deviations for continuous variables. Statistical analysis was performed using the Statistical Package for Social Sciences (Build 1.0.0.642, Version 25) (IBM, New York, USA). Categorical data were compared using chi-squared estimates and continuous data were compared using an unpaired Student’s t-test. Multivariate Cox proportional hazards analysis was performed to identify predictors of MACE at 12 months. A forward likelihood ratio method was used to enter variables into the regression model including age ≥75, gender, cardiovascular risk factors, STEMI presentation, access site, multivessel coronary disease, prior PCI or CABG, use of P2Y<sub>12</sub> receptor inhibitors, use of drug-eluting (DES) or bare metal stents (BMS), cardiogenic shock, and cardiac arrest.

3. Results

Between January 2011 and December 2017, 3624 patients with ACS were treated with PCI either via TFA (n = 2391) or TRA (n = 1233). Analysis of demographic data (Table 1) demonstrated that patients in the TRA group were younger (63.2 ± 12.1 years vs 65.5 ± 12.5 years; p < 0.0001) and had a lower percentage of females (20.1% vs 24.6%; p = 0.0019)
During this study, there was only 1 reported case of BARC 3 bleeding events (0.41% vs 1.0%; $p = 0.1183$).

A greater reduction in mortality at 12 months (3.0% vs 6.3%; $p < 0.0001$) was observed. In addition, the TRA group demonstrated lower rates of MI (1.8% vs 3.9%; $p = 0.0004$), CABG (0.6% vs 1.5%; $p = 0.0205$), TLR (1.0% vs 2.9%; $p < 0.0001$), large haematoma (0.4% vs 1.8%; $p = 0.0003$), BARC 2 (0.24% vs 1.09%; $p = 0.0029$), and BARC 3 bleeding events (0.41% vs 1.0%; $p = 0.0426$).

Table 1: Patient demographics.

| Variable                  | TFA group | TRA group | $p$ value |
|---------------------------|-----------|-----------|-----------|
| Overall population        | 2391 (66.0%) | 1233 (34.0%) | $<0.0001^*$ |
| Age (years), mean ± SD    | 65.5 ± 12.5 | 63.2 ± 12.1 | $0.009^*$ |
| Female, n (%)             | 585 (24.6%) | 246 (20.1%) | $0.1408$ |
| Diabetes, n (%)           | 547 (22.9%) | 254 (20.6%) | $0.4827$ |
| Diabetes treated with insulin | 118 (4.9%) | 61 (5.0%) | $1.0000$ |
| Hypertension, n (%)       | 1331 (55.7%) | 664 (53.9%) | $0.3068$ |
| Smoker, n (%)             | 522 (21.8%) | 330 (26.8%) | $0.001^*$ |
| Ex-smoker, n (%)          | 692 (28.9%) | 380 (30.8%) | $0.2492$ |
| Hypercholesterolaemia, n (%) | 1053 (44.0%) | 537 (43.6%) | $0.8047$ |
| Family history of CVD, n (%) | 646 (27.0%) | 391 (31.7%) | $0.0032^*$ |
| Body Mass index, mean ± SD | 28.4 ± 5.1 | 29 ± 5.7 | $0.0048^*$ |
| eGFR, mean ± SD           | 74.9 ± 19.2 | 78.1 ± 16.1 | $0.007^*$ |

Statistically significant ($p < 0.05$). TFA = transfemoral artery access. TRA = transradial artery access. SD = standard deviation. CVD = cardiovascular disease. eGFR = estimated glomerular filtration rate.

4. Discussion

The publication of the major RCTs of TRA versus TFA in ACS [11, 12, 17, 18] has been accompanied by a steady increase in the adoption of TRA in many institutions [15, 16], including ours. Transradial artery access PCI for ACS at our institution steadily increased to over 60% of cases in a period of six years, representing the evolution of a major trend in interventional cardiology. This study represents our early experience with TRA but has already demonstrated that TRA was an independent predictor of reduced MACE at 12 months (RR = 1.8; CI = 1.33–2.48; $p < 0.0001$). Other independent predictors of MACE included cardiogenic shock, cardiac arrest, age $\geq 75$, multivessel coronary disease, prior PCI, and use of BMS.

Overall results from RCTs suggest that TRA is associated with a lower risk of mortality in ACS but not in patients with stable ischaemic heart disease [10]. The RIVAL study did not find a significant difference in mortality between TRA and TFA, but mortality was significantly lower in the prespecified STEMI subgroup [12]. The MATRIX [11] and RIFLE-STEACS [17] trials found a lower mortality rate with TRA compared to TFA. The weighted mortality rate in patients with ACS was also demonstrated to be lower in TRA (2.7% vs 3.7%; $p < 0.05$) in a recent meta-analysis [10]. This translates to 10 fewer deaths for every 1000 patients with ACS undergoing TRA PCI.
The reasons behind a lower incidence of MACE with TRA remain unclear and likely multifactorial. One reason may be due to a reduction in bleeding events. Post-PCI bleeding is significant due to its association with worse clinical outcomes. Patients with ACS are generally treated with potent anticoagulant and antiplatelet agents and will have a higher risk of access site and nonaccess site bleeding compared with stable patients. Major bleeding events such as gastrointestinal or intracranial haemorrhage may necessitate interruption of antithrombotic medications, increasing the risk of stent thrombosis or other thrombotic events. Results from the one-year outcomes of the PRAGUE-18 study demonstrated that premature discontinuation of antiplatelet therapy was associated with significantly higher adverse events [26]. Additionally, blood transfusions used in the management of major bleeding have been linked with adverse short-term and long-term mortality [4].

Earlier mobility associated with TRA PCI may also drive a lower incidence of MACE. Earlier mobility and ultimately earlier discharge reduces the risk of venous thromboembolism and hospital-acquired complications [10]. In the same vein, lower rates of acute kidney injury with TRA result in shorter admissions and reduce the risk of chronic kidney disease [27].

Our study highlights several unique findings. Firstly, the reduction in MACE on univariate analysis was driven by several components including mortality, recurrent MI, TLR, and CABG. This is a novel finding given that, in a recent meta-analysis, a reduction in MACE with TRA was driven mainly by a reduction in mortality [28]. However, it is

| Overall population  | TFA group | TRA group | p value |
|---------------------|-----------|-----------|---------|
| Prior PCI, n (%)    | 572 (24.8%) | 252 (20.8%) | 0.0093* |
| Prior CABG, n (%)   | 268 (11.5%) | 32 (2.7%) | <0.0001* |
| GPI use             | 281 (11.8%) | 53 (4.3%) | <0.0001* |
| Cardiogenic shock   | 123 (5.1%) | 37 (3.0%) | 0.0027* |
| Cardiac arrest      | 68 (2.8%) | 16 (1.3%) | 0.0033* |
| Indication          |           |           | <0.0001* |
| NSTEMI              | 890 (38.8%) | 577 (47.3%) |         |
| STEMI               | 1113 (48.6%) | 489 (40.1%) |         |
| Unstable angina     | 289 (12.6%) | 154 (12.6%) |         |
| Number of diseased vessels | 1203 (51.4%) | 638 (52.6%) | 0.5 |
| Pre-stent intervention |           |           | <0.0001* |
| Graft               | 89 (3.7%) | 11 (0.9%) |         |
| Left main           | 44 (1.8%) | 8 (0.7%) |         |
| LAD/Diagonal        | 937 (39.3%) | 480 (38.9%) |         |
| LCx                 | 550 (23.0%) | 298 (24.2%) |         |
| RCA                 | 767 (32.1%) | 436 (35.4%) |         |
| Stent type          |           |           | <0.0001* |
| Balloon only        | 210 (8.8%) | 98 (8.0%) |         |
| BMS                 | 1056 (44.2%) | 288 (23.4%) |         |
| DES                 | 1125 (47.1%) | 847 (68.7%) |         |
| B2/C coronary lesion type | 1786 (77.4%) | 876 (73.2%) | 0.0076* |
| Prasugrel/ticagrelor use, n (%) | 540 (22.6%) | 318 (25.8%) | 0.0321* |
| Procedural success  | 2310 (96.6%) | 1207 (97.9%) | 0.0275* |
| Vascular closure device use | 1375 (57.5%) | N/A | <0.0001* |
| Contrast volume, mL | 144.2 | 133.6 | <0.0001* |
| Intra-aortic balloon pump use | 26 (1.1%) | 1 (0.9%) | <0.0001* |
| TIMI flow           |           |           | 0.058 |
| TIMI 0              | 42 (1.8%) | 11 (0.9%) |         |
| TIMI I              | 13 (0.6%) | 7 (0.6%) |         |
| TIMI II             | 65 (2.8%) | 23 (1.9%) |         |
| TIMI III            | 2208 (94.9%) | 1166 (96.6%) |         |
| Stent thrombosis    |           |           |         |
| Early (0–30 days)   | 9 (56.3%) | 5 (71.4%) | 0.487 |
| Late (30–365 days)  | 6 (37.5%) | 2 (28.6%) | 0.676 |
| Very late (>365 days) | 1 (6.25%) | 0 (0%) | 0.388 |

Statistically significant (p < 0.05). TFA = transfemoral artery access. TRA = transradial artery access. PCI = percutaneous coronary intervention. CABG = coronary artery bypass graft. GPI = glycoprotein IIb/IIIa inhibitor. STEMI = ST-segment elevation myocardial infarction. NSTEMI = non-ST-segment elevation myocardial infarction. LAD = left anterior descending. LCx = left circumflex. RCA = right coronary artery. BMS = bare metal stent. DES = drug-eluting stent. TIMI = thrombolysis in myocardial infarction.
possible that lower rates of MI and TLR observed in our TRA group may be related to higher use of newer P2Y<sub>12</sub> inhibitors and DES in this group. Secondly, our results arise from a centre wherein TRA was in its infancy and a significant learning curve existed as operators became familiar with the technique. We do not have accurate information on the rate of access site-switching; however, the estimated rate in the first two years was approximately 5%. Ultimately, this translates into a significant clinical benefit for TRA in a real-world consecutive cohort of ACS patients. Furthermore, we observed that improved clinical outcomes were demonstrated with TRA in the management of all subtypes of ACS and not limited to STEMI. It is likely that the relative benefit of TRA may be more pronounced when it is utilised in higher risk groups such as the elderly, females, extremes of BMI, and those with significant comorbidities [10].

Following the spawn of literature demonstrating the clinical benefits of TRA in ACS, TRA has been recommended as first-line PCI access route in the Australian [1], European [29], and US [10] guidelines. However, resistance

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**Table 3: Unadjusted analysis of procedural outcomes at 12 months.**

|                      | TFA group | TRA group | p value | Likelihood ratio |
|----------------------|-----------|-----------|---------|-----------------|
| Death                | 150 (6.3%)| 37 (3.0%) | <0.0001*| 19.4            |
| Stent thrombosis     | 16 (0.7%) | 7 (0.6%)  | 0.82    | 0.135           |
| Myocardial infarction| 93 (3.9%) | 22 (1.8%) | 0.0004* | 12.9            |
| Target lesion        | 69 (2.9%) | 12 (1.0%) | <0.0001*| 15.6            |
| CABG                 | 35 (1.5%) | 7 (0.6%)  | 0.0205* | 6.4             |
| Haematoma            | 42 (1.8%) | 5 (0.4%)  | 0.0003* | 14              |
| BARC 2 bleeding events| 26 (1.1%)| 3 (0.2%)  | 0.0029* | 8.9             |
| BARC 3 bleeding events| 24 (1.0%)| 5 (0.4%)  | 0.0426* | 4.1             |

Statistically significant (p < 0.05). TFA = transfemoral artery access. TRA = transradial artery access. CABG = coronary artery bypass graft. BARC = Bleeding Academic Research Consortium.

**Table 4: Multivariate analysis of independent predictors of MACE at 12 months (Cox proportional hazard).**

|                      | Risk ratio | 95% confidence interval | p value |
|----------------------|------------|-------------------------|---------|
| Age ≥ 75             | 1.9        | 1.49–2.49               | <0.0001*|
| Female versus male   | 1.1        | 0.80–1.40               | 0.66    |
| TFA versus TRA       | 1.8        | 1.33–2.48               | <0.0001*|
| Prior PCI            | 1.6        | 1.19–2.04               | 0.0013* |
| Cardiogenic shock    | 3.3        | 2.19–4.88               | <0.0001*|
| Cardiac arrest       | 3.0        | 1.73–4.89               | 0.0002* |
| DES versus BMS       | 0.6        | 0.47–0.77               | <0.0001*|
| Two-to-three vessel disease | 1.7 | 1.33–2.17 | <0.0001* |

Statistically significant (p < 0.05). TFA = transfemoral artery access. TRA = transradial artery access. PCI = percutaneous coronary intervention. DES = drug eluting stent. BMS = bare metal stent.
to TRA persists. It has been suggested that better results obtained by TRA in the MATRIX trial were only apparent in high volume TRA centres, whose operators may have a perceived lower proficiency with TFA [6]. Our study represents encouraging results of an institution in transition from TFA to TRA (TRA = 2% in 2011 to 60% in 2017), with operators who were already skilled in TFA, gaining experience with TRA through the course of this study.

One of the caveats of the MATRIX trial was the use of GPls [6], which is associated with increased bleeding and mortality [30]. In line with a global trend, our use of GPls was declining during the period of this study. Overall usage of GPls was 4.3% with TRA and 11.8% with TFA. We adjusted for the use of GPls in our multivariate model and believe that a higher use of GPls with TFA did not skew the observed benefits in the TRA group.

Other factors that may have contributed to higher risk of bleeding complications in older PCI trials include the use of larger sheaths and low usage of VCDs. Use of VCDs has been associated with a significant reduction in the risk of bleeding complications [31]. These were only used in 25.6% of TFA cases in the RIVAL study [12] and their use was not reported in the MATRIX study [11]. On the other hand, our operators rarely used sheaths larger than 6-French, and VCDs were utilised in 60% of TFA cases, which is consistent with the frequency of usage of these devices in current studies. It is possible that higher usage of VCDs in our cohort may have reduced bleeding complications in the TFA group.

More recently, the SAFARI-STEMI trial failed to demonstrate any significant difference in 30-day mortality or bleeding complications between TRA and TFA primary PCI for STEMI patients [32]. Factors which may have reduced bleeding risk in SAFARI-STEMI included exclusion of postlysis and anticoagulated patients, predominant use of bivalirudin instead of heparin, avoidance of large femoral sheaths, and maximising the use of VCDs. Recruitment to the study was difficult and slow, eventually leading to premature cessation of the trial due to futility. Under these circumstances, it is likely that the randomised cohort represented a low-risk STEMI population, as operators may have been reluctant to randomise high bleeding risk patients (e.g., elderly or frail patients). Comparing TRA and TFA groups, the mean age was 61.6 versus 62.0; Killip Class II–IV demonstrated in 7% versus 6.7%, and 30-day mortality was 1.5% versus 1.3% (p = 0.69%). If appropriate steps are taken to reduce bleeding risk as was done in the SAFARI-STEMI trial, the choice of vascular access does not significantly impact clinical outcomes in a relatively low-risk population of STEMI patients. While this notion is intuitive, the caveat is that certain components of the trial such as their exclusion criteria are not representative of routine day-to-day interventional practice, making it unlikely that their results can be translated into a real-world setting.

4.1. Limitations. The nonrandomised study design does not allow for the control of confounders between TRA and TFA groups. Interventionists may have favoured the use of TFA in the early part of their learning curve for STEMI or CABG patients, those with cardiac arrest or cardiogenic shock, elderly patients, and females. Use of DES was rapidly increasing during our study period of 2011–2017 in parallel with the rise in TRA and this resulted in greater overall usage of DES in the TRA cohort. However, we adjusted for all these variables in our multivariate model and still found a lower incidence of MACE with TRA. We acknowledge that due to the observational nature of the study and presence of multiple confounders, it is difficult to draw any firm conclusions regarding the effect of TRA on one-year MACE. This study spans over a decade and it is possible that PCI results naturally improved over time due to advancements in stent technology and antiplatelet agents, which may, in part, favour the outcomes in the TRA group. The data presented in this study were representative of our institution’s clinical practice and may not be generalisable to other PCI centres. Finally, the retrospective study design prevents the capacity to audit the quality of patient data entered. However, data were collected at the time of the procedure by experienced technicians and are therefore likely to be accurate.

5. Conclusion

Transradial artery access was found to be an independent predictor of lower MACE and bleeding events at 12 months in consecutive patients with ACS treated with PCI. However, due to the observational nature of our study and the presence of multiple confounders, we caution against a definitive conclusion. Our findings from a real-world setting with consecutive patients and no exclusion criteria in an institution transitioning to TRA are in line with results of major RCTs. As such, we feel that our results support the use of TRA as the preferred access site in patients undergoing PCI for ACS to improve patient outcomes.

Data Availability

In order to maintain patient privacy and confidentiality, data are not freely available for sharing.

Disclosure

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors.

Conflicts of Interest

The authors have no conflicts of interest in the publication of this manuscript.

Authors’ Contributions

All authors are in agreement with the manuscript.
Acknowledgments

The authors acknowledge the assistance of all doctors, nurses, technicians, paramedics, and hospital staff who cared for our patients.

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