Trends In Intraaortic Balloon Counterpulsation: Comparison Of A 669 Record Australian Dataset With The Multinational Benchmark Counterpulsation Outcomes Registry

Short title: IABP trends of an Australian Hospital

Key words: assisted circulation; cardiac output, low; shock; myocardial ischaemia; thoracic surgery; records.

This study was undertaken at The Prince Charles Hospital, Brisbane, Australia. Staff within the General Intensive Care Unit were responsible for the design, development and implementation of this study.

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SUMMARY

The aim of this study was to review and describe indications for intraaortic balloon counterpulsation (IABP) use and identify the impact these have on outcomes at an Australian cardiothoracic tertiary referral hospital. A secondary aim was comparison of the Australian practice with a large multinational IABP data registry. Patient demographics, IABP indication, IABP complication rate and mortality in 662 patients treated with IABP at The Prince Charles Hospital (TPCH), Brisbane between January 1994 and December 2004 inclusive were compared with The Benchmark Counterpulsation Outcomes Registry. Data were collected between 1994 and 2000 by retrospective patient record review and prospectively using the Benchmark database from 2001 to 2004. Statistical analysis was undertaken using SAS (v8.2) software. The mean age of patients managed with IABP at TPCH (71.6% male) was 63.4 years (SD 12.4). In-hospital mortality rate was 22% and the complication rate was 10.3%. TPCH indications for IABP were: weaning from cardiopulmonary bypass (34.2%); cardiogenic shock (24.4%); preoperative support (13%); catheter laboratory support (10.6%); refractory ventricular failure (7.3%); ischaemia related to intractable ventricular arrhythmias (4.5%); unstable refractory angina (4%); mechanical complications due to acute myocardial infarction (1.2%); and other (0.4%) (0.4% not reported). In comparison to Benchmark, IABP at TPCH demonstrated a prejudice toward intraoperative use (34.2% versus 16.6%; P=<0.0001) and an aversion to catheter laboratory support (10.6% versus 19%; P=<0.0001). TPCH and Benchmark IABP outcomes demonstrated comparable mortality (22% versus 20.8%; P=ns) but increased TPCH complications (10.3% versus 6.2%; P=<0.0001) owing to a 2% difference in observed insertion site bleeding.

INTRODUCTION

Diastolic augmentation to assist in the treatment of left ventricular failure was described for the first time in 1958.[1] Harken suggested that the rapid removal of blood from the femoral artery during systole and it's replacement during diastole would assist cardiac output and unload the heart simultaneously.[1, 2] Considering these principles an intraaortic balloon pump (IABP) prototype was developed in 1962 and integrated into patient care in 1968.[3, 4] Initial clinical experience was mixed; while an improvement in haemodynamic function was demonstrated, mortality rates were not significantly altered. Since 1968 IABP development has continued and practice has consequently changed dramatically. IABP has progressed to become an established treatment widely used in the setting of cardiac failure and potential cardiac compromise. There have been major improvements in patient outcome as well as dramatic reductions in morbidity and mortality rates.[5] Technological advance has allowed easier intraaortic balloon (IAB) catheter insertion, the provision of smaller catheters and a more efficient drive console resulting in greater circulatory benefits for the patient.[6] Time has also seen a change in IABP indications.

Traditionally indications for IABP have included cardiogenic shock, myocardial ischaemia, failure to separate from cardiopulmonary bypass and severe acute mitral regurgitation.[7] The increasing use of IABP, however, has seen its scope evolve to include additional applications such as the provision of haemodynamic support during or after cardiac catheterisation, preoperative insertion in high risk patients, the treatment of refractory unstable angina, refractory ventricular failure and ischaemia related to intractable ventricular arrhythmias.[8] Diversity of IABP use has also seen success in the augmentation of cerebral blood flow in a setting of cerebral vasospasm, in the anaesthetic management of high risk cardiac patients undergoing non cardiac surgery, in the management of myocardial failure following severe post partum haemorrhage and for circulatory support in septic shock.[9-15]

Papers demonstrate significant variance in practice between United States and non United States hospitals with differences in IABP utilisation rates, indications and outcomes.[16] The purpose of this study was to review and describe current indications for IABP use and the impact these have on outcomes at an Australian cardiothoracic tertiary referral hospital. Recent establishment of large multinational registries containing data on IABP has afforded an opportunity for contrasting local practice.[5, 8, 17, 18] A secondary aim of this study was the comparison of aspects of application and outcomes at The Prince Charles Hospital (TPCH) with those of a large multinational IABP data registry. To meet these aims this study set out to answer the following research questions:

1. What are the characteristics of TPCH IABP (including patient demographics and characteristics)?
2. What are the mortality and complication rates for IABP at TPCH?
3. Does IABP application and outcome significantly differ between TPCH and The Benchmark Counterpulsation Outcome Registry?

MATERIALS AND METHODS

Study patients and setting

TPCH is a 450 bed, metropolitan, government funded public, tertiary referral, teaching hospital, with a predominantly cardiothoracic medical and surgical case-mix. It incorporates a 16 bed coronary care unit, a dedicated 10 bed cardiac surgical intensive care unit (ICU) and an eight bed general ICU. Admission to the coronary care unit or either ICU depends upon the complexity of the patient condition and cardiological or surgical intervention.

This study reports data related to 669 IABP catheter insertions in 662 patients. While 674 patients were managed with 683 consecutive IABP at TPCH between January 1, 1994 and December 31, 2004, data were unavailable for 12 patients (14 IABP insertions). All counterpulsation was employed using System 90, 90T, 97 or 98XT drive consoles and Datascope, Statgaurd, Profile 8 or Fidelity IABP catheters (8 French to 9.5 French). After obtaining both hospital and university ethical committee approval these patients were identified from the intensive care, cardiac surgical and cardiac catheter laboratory databases. Data were collected retrospectively from 1994 to 2000 and prospectively using the Benchmark Counterpulsation Outcomes Registry database from 2001 to 2004. Individual patient hospital records were reviewed for missing data. Patients receiving an IABP at a referring institution prior to transfer and retaining this device upon TPCH admission were included in this study. Patient demographics, APACHE II score, admission diagnosis, co-morbidities, IABP indication, IABP complications, location of catheter insertion, interventional cardiology and surgical procedures, mechanical ventilation, arrhythmia's, ICU outcome and hospital outcome were collected.

Classifications

IABP mortality was defined as an all-cause (any cause during or after IABP) in-hospital mortality. Insertion indications were: preoperative support in the high risk patient undergoing coronary artery bypass graft (requiring catheter insertion prior to aortic cross clamping); post cardiopulmonary bypass (intraoperative IAB catheter insertion and the commencement of IABP due to difficulties weaning the patient from cardiopulmonary bypass, or IABP during the recovery phase due to postcardiotomy failure); cardiogenic shock (ejection fraction < 40% combined with systolic blood pressure < 90mmHg for ≥ 1 hour, unresponsive to fluid administration alone); catheter laboratory support (IAB catheter insertion in the catheter laboratory prior to or during a procedure); unstable refractory angina; refractory ventricular failure; ischaemia related to intractable ventricular arrhythmias; mechanical complications due to acute myocardial infarction; and other (indications not fitting the above counterpulsation indications). Complications were: bleeding (IAB catheter insertion site bleeding and haematoma); balloon failure (IAB rupture, leak, poor inflation or poor augmentation); limb ischaemia; limb amputation; and balloon entrapment.

Statistical analysis and comparison

Patient demographics and characteristics were compared using chi square, Fisher's exact (X^2) and student's *t* test with correction for multiple comparisons. Calculations were performed using version 8.2 of the SAS software package. Wherever possible results were expressed as mean ± standard deviation (SD). Data from TPCH were compared with data from The Benchmark Counterpulsation Outcomes Registry. (The Benchmark Counterpulsation Outcomes Registry is the largest IABP registry providing perpetual, prospective IABP data on patients treated at 260 hospitals in 18 countries. However, despite the involvement of 18 countries, the majority of data represents practice in the United States [85% of total patient enrolments] and to a lesser degree Europe [11% of total patient enrolments]).[5] The comparative Benchmark Counterpulsation Outcomes Registry data were collected between 1996 (registry inception) and 2004 inclusive.

RESULTS

What are the characteristics of TPCH IABP (including patient demographics and characteristics)?

Baseline clinical characteristics for the total TPCH population and IABP indications are shown in Table 1. Participants were aged between 14 and 89 years. Of the 669 TPCH IABP cases, 599 were admitted to an ICU with a mean ICU length of stay of 99.8 hours (SD 125.3; range 1-1252). Eighty five percent of IABP patients cared for in ICU received mechanical ventilation for a mean of 59.3 hours (SD 98.7). Of those IABP patients not admitted to an ICU, 64 were managed in the coronary care unit only while 6 died in the operating room.

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During the study period, 431 patients treated with IABP underwent cardiac surgery representing a 2.4% use rate of cardiac surgical IABP (17,785 cardiac surgical operations were performed between 1994 and 2004 at TPCH). IABP utilisation at TPCH increased by 572% from 1994 (22 insertions) to 2004 (126 insertions) (Figure 1).

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IAB insertion was performed in the catheter laboratory (43.8%), the operating room (42.2%), the ICU or coronary care unit (10.4%), other hospitals (2.1%) and in other locations (0.9%) (not recorded: 0.6%). The predominant catheter size was 40 millilitre volume (43%). Fifty percent of catheters were sheathed while 31% were unsheathed (19% of cases were unrecorded). A percutaneous approach was used in 97% of cases with only one patient subject to a trans-aortic approach and three patients requiring placement with surgical cutdown (2.8% not recorded).

What are the mortality and complication rates for IABP at TPCH?

Total TPCH IABP in-hospital mortality was 22% with an overall ICU mortality of 15.9%. Between 1994 and 2004 in-hospital mortality decreased while APACHE II scores increased (Figure 2). In this series the APACHE II score demonstrated a linear relationship with in-hospital mortality despite a predominance of cardiothoracic patients (Figure 3). Total TPCH complication rate was 10.3%. No limb amputation was required in the TPCH series. All IABP outcomes are shown in Table 2.

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Does IABP application and outcome significantly differ between TPCH and The Benchmark Counterpulsation Outcome Registry?

The difference between TPCH and Benchmark IABP application and outcomes is shown in Tables 1 and 2. TPCH was more likely to utilise IABP than Benchmark in the setting of: weaning from cardiopulmonary bypass; cardiogenic shock; and ischaemia related to intractable ventricular arrhythmias. TPCH was less likely to utilise IABP than Benchmark in the setting of: catheter laboratory support; unstable refractory angina; and mechanical complications due to acute myocardial infarction. TPCH demonstrated greater survival rates than Benchmark in the setting of: weaning from cardiopulmonary bypass; refractory ventricular failure; and mechanical complications due to acute myocardial infarction. TPCH survival was poorer than Benchmark in the settings of preoperative support in the high risk patient undergoing coronary artery bypass surgery and ischaemia related to intractable ventricular arrhythmias. IABP complication rates were higher in the TPCH series than Benchmark owing to an increased rate of access site bleeding.

DISCUSSION

The pre-emptive use of IABP is gaining popularity.[16] Beginning with preoperative support of high risk patients undergoing coronary artery bypass graft surgery, practice has developed to incorporate support during percutaneous coronary intervention as a principal IABP indication. The growing acceptance surrounding pre-emptive IABP and earlier intervention in the course of patient illness has seen a dramatic increase in the overall use of the IABP. Use of the IABP at TPCH has increased by almost 600% between 1994 and 2004 (Figure 1). Despite TPCH increasing pre-emptive IABP use in the settings of catheter laboratory support and preoperative support over the 11 years, weaning from cardiopulmonary bypass remains the principal indication. A comparison of IABP indications between TPCH and Benchmark found most to demonstrate statistical difference, significant clinical difference, however, lay only in two areas. In contrast to Benchmark, TPCH application of IABP was greater when weaning from cardiopulmonary bypass and fewer when supporting catheter laboratory procedures. Many reasons have been proposed for variations in IABP practice including controversy concerning the indications for use and differing philosophies on management for specific clinical indications.[19-21] Additionally IABP is still regarded and registered as a complication rather than a therapy.[21] It is likely the variation between TPCH and Benchmark indications represents a lack of consensus on the indications for IABP use.

Reflecting the change in IABP practice, TPCH – like The Benchmark Counterpulsation Outcomes Registry – has demonstrated a decrease in mortality rates as well as an increased use (Figure 1). Improvement in TPCH mortality was demonstrated despite an escalation in APACHE II scores (Figure 2). While the APACHE II score is a general severity of illness measure not originally calibrated for cardiac surgical patients, its predictive power has shown to be discriminatory.[22-24] In this series the APACHE II score demonstrated a linear relationship with in-hospital mortality despite a predominance of cardiothoracic patients (Figure 3). Considering this, uniform application of a general measure of patient acuity such as APACHE II instead of the Parsonnet score, may be appropriate in the cardiothoracic setting.

Encouragingly, comparison of IABP outcomes between TPCH and Benchmark over this 11 year series demonstrates an equivalence of in-hospital mortality. Examining mortality by indication, however, revealed TPCH to have a significantly lower mortality associated with weaning from cardiopulmonary bypass and a higher mortality in the setting of preoperative support. It is interesting to note TPCH intraoperative application is almost 20% higher than that of Benchmark. While trends of TPCH practice over the past 11 years indicate greater application of pre-emptive IABP, it is apparent TPCH practitioners are more likely to undertake IABP intraoperatively than preoperatively, suggesting the superior outcome for intra/postoperative patients in the TPCH series cannot readily be dismissed on the basis of excluding critically ill poorer surgical candidates. While it could be argued those TPCH patients receiving intra/postoperative IABP were of a lower acuity as they were stable enough preoperatively to not require IABP, patient characteristics in both TPCH and Benchmark series were similar indicating this was not the case (Table 1). Additionally, TPCH's higher intraoperative application most likely reflects a reluctance to insert IABP pre-emptively in the surgical setting, necessitating employment following the surgery when difficulty arises with bypass separation. This interpretation would imply TPCH are inserting IABP later, into patients of greater acuity. One might consider TPCH to be a high end user of the IABP with frequent use leading to experienced practitioners. The importance of frequent use of the IABP and therefore experience with its use should not be underestimated.[25] Recent research suggests a volume outcome relationship with improved mortality at high volume centres.[26] The authors are unsure as to whether or not this has any impact upon mortality following cardiopulmonary bypass.

While TPCH complication rate was 10.3%, no major complications were demonstrated. There was no mortality directly attributable to counterpulsation, no limb amputations and no peripheral thromboembolism complications. Additionally, overall complication rates reduced over time from 9% in 1994, to 3.9% in 2004 when TPCH insertion rates were at their highest. For the 11 year period, however, TPCH overall complications were 4.1% higher than those of the Benchmark Counterpulsation Outcomes Registry. While the incidence of IABP complications presented in recent experience is generally low,[5, 8, 16, 18, 25, 27] TPCH is not on its own reporting a rate in excess of 10%.[27-29] It should be noted TPCH complication rates are comparable or lower to those of Benchmark in all complication aspects barring access site bleeding. The comparison of complications between institutions becomes problematic because the definition of what constitutes a complication involves some degree of subjectivity. While access site bleeding is a common complication, some studies fail to identify bleeding as a complication within their series, despite listing other IABP complications such as limb ischaemia as problematic.[30] Complication rates will vary dramatically depending on selective reporting, or as is the case with access site bleeding, anticoagulation protocols.

Study limitations

Comparison between TPCH and The Benchmark Counterpulsation Outcomes Registry could be seen as potentially flawed. Owing to the voluntary nature of Benchmark Counterpulsation Outcomes Registry involvement, results may not be representative of the entire spectrum of clinical practice. Additionally, as could be expected with any large scale multinational registry, any site to site variation in personnel or resources allocated to the registry may impact upon the accuracy of some records. It must also be considered all data is observational and some TPCH data has been collected retrospectively. Furthermore, owing to the retrospective nature of this study, it is recognised comparison of IABP usage and outcomes for individual indications does not reflect overall management of that particular indication, but rather distribution of overall IABP use in relation to the indication.

Concluding remarks

The greatest use of pre-emptive IABP occurs within the United States.[16] This impacts heavily upon the results of The Benchmark Counterpulsation Outcomes Registry with 84.7% of contributing patients based in US centres. While this recent trend of pre-emptive IABP has been adopted at TPCH, insertion following cardiopulmonary bypass remains high, while supportive use within the catheter laboratory is comparatively low. Despite the variance in IABP indication between TPCH and The Benchmark Counterpulsation Outcomes Registry, mortality – the primary treatment outcome – is comparable.

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LIST OF TABLES AND FIGURES

TABLE 1: Baseline Clinical Characteristics and Counterpulsation Indication of Patients Treated With IABP.

Variable	TPCH	Benchmark	*P* value
Total population (n)	669	38,606	
Age, mean (SD), yrs	63.4 (12.4)	65.5 (12.2)	
Proportion of women	28.4%	32.3%	
Ejection fraction, mean (SD)	39.7 (17.2)	37.1 (16)	
Prior myocardial infarction	31.8%	29.1%	
History of diabetes	21.2%	23.6%	
Prior sternotomy	14.5%	13.8%	
Peripheral vascular disease	12.6%	10.2%	
APACHE II score, mean (SD)	18.3 (7.4)	n/a	
IABP duration, hours, mean (SD)	46.3 (32.8)	59	
ICU length of stay, mean (SD), hrs	99.8 (125.3)	n/a	
Hospital length of stay, mean (SD), days	18.9 (24.2)	15	
Indication			
Weaning from cardiopulmonary bypass	34.2%	16.6%	<0.0001
Cardiogenic shock	24.4%	20.6%	0.02
Preoperative support in high risk patient undergoing CABG	13%	14.9%	ns
Catheter laboratory support	10.6%	19%	<0.0001
Refractory ventricular failure	7.3%	6.9%	ns
Ischaemia related to intractable ventricular arrhythmias	4.5%	1.6%	<0.0001
Unstable refractory angina	4%	10.9%	<0.0001
Mechanical complications due to AMI	1.2%	5.7%	<0.0001
Other	0.4%	3%	0.0001
Not reported	*0.4%*		

Footnote: n/a = not available; ns = not significant.

TABLE 2: IABP In-hospital Mortality by Counterpulsation Indication and Complication Rates.

Assessment	TPCH	Benchmark	*P* value
Total in-hospital mortality	22%	20.6%	ns
Weaning from cardiopulmonary bypass	15.7%	20%	0.005
Cardiogenic shock	41.1%	37.7%	ns
Preoperative support in high risk patient undergoing CABG	12.6%	5.1%	<0.0001
Catheter laboratory support	8.5%	10%	ns
Refractory ventricular failure	16.3%	30.5%	<0.0001
Ischaemia related to intractable ventricular arrhythmias	46.7%	24.9%	<0.0001
Unstable refractory angina	7.4%	7.8%	ns
Mechanical complications due to AMI	12.5%	26.1%	<0.0001
Overall complication rate	10.3%	6.2%	<0.0001
Any access site bleeding	4.5%	2.5%	0.001
Balloon failure	2.8%	2.9%	ns
Limb ischaemia	1.5%	2.7%	0.05
Balloon entrapment	1%	1.1%	ns
Other	0.4%	1.2%	ns

Footnote: ns = not significant.

FIGURE 1: TPCH IABP Cases and In-hospital Mortality by Year.

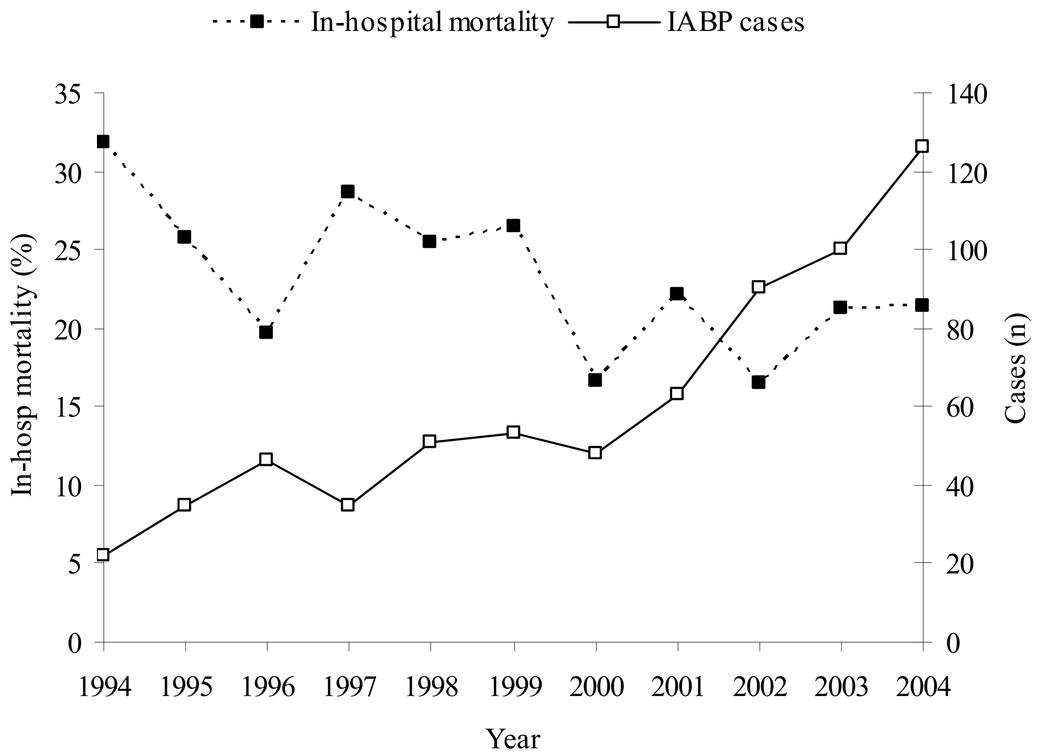


FIGURE 2: TPCH IABP In-hospital Mortality Versus Mean APACHE II Score by Year.

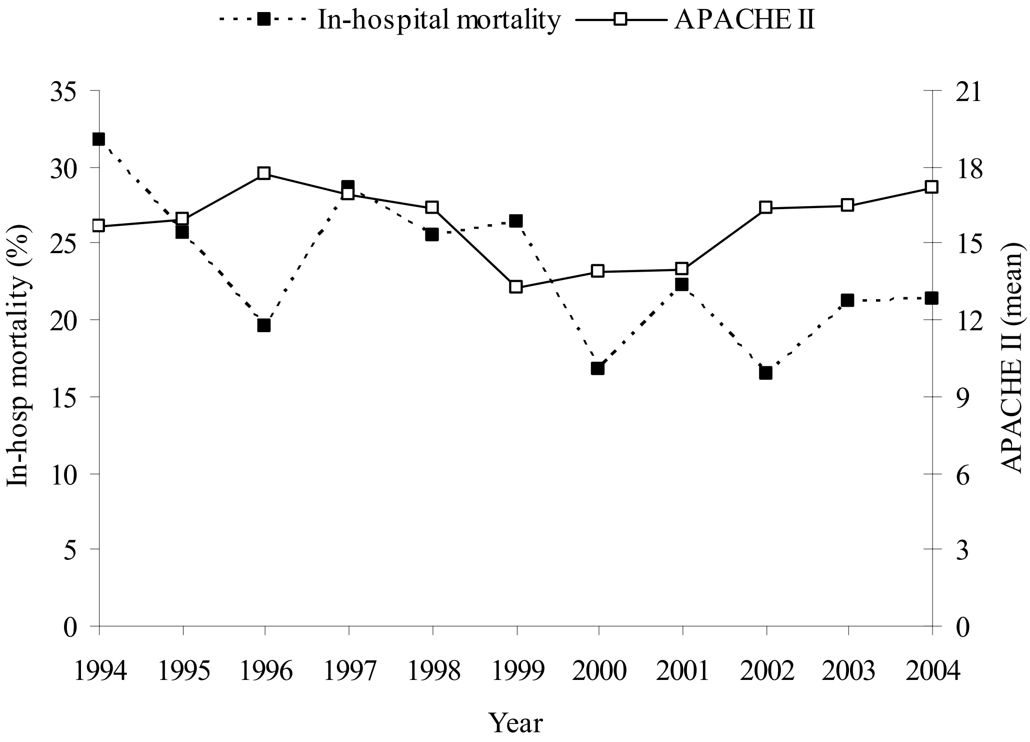
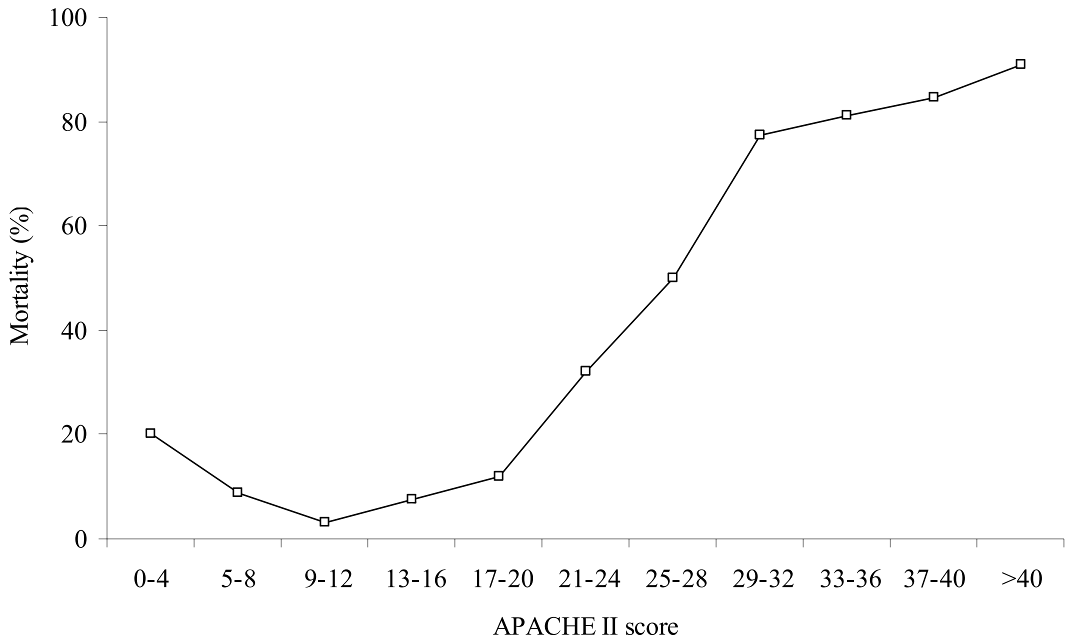


FIGURE 3: TPCH IABP In-hospital Mortality Versus APACHE II Score.



Footnote: Mortality for the APACHE II groups 0-4 and 5-8 constituted three patients only. All died in ICU shortly following admission and received low scores due to a lack of physiological data.