Outcome at thirty days for low risk chest pain patients assessed using an Accelerated Diagnostic Pathway in the Emergency Department.

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undertook recruitment and patient contact, and managed the data, including quality control. RM analyzed the data. DG and RM drafted the manuscript, and all authors contributed substantially to its revision. RM takes responsibility for the paper as a whole.

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ABSTRACT:

Study objectives:

Primary: to determine incidence of 30-day major adverse cardiac events (MACE), in patients discharged from the ED following assessment using an Accelerated Diagnostic Pathway (ADP).

Secondary: to determine incidence of 30-day MACE for all ADP patients.

Methods:

Monash Health ED patients thought at low risk for AMI or hospital admission are assessed using an ADP, based on arrival and 90 minute point-of-care (POC) cTnI and myoglobin concentration. Other patients are assessed using a traditional pathway of arrival and six hour central lab cTnI. Choice of pathway is based on the clinical judgement of the attending ED doctor. To investigate the safety of the ADP component, an observational study of all ADP patients presenting from 6 June 2013 to 30 September 2013 was conducted. After 30 days, occurrence of MACE was determined by examination of hospital records or telephone contact with patients who had not returned.

Results:

Of 1,547 eligible patients, 1,384 (89.5%) were followed up. Of the 1,143 discharged patients with follow-up information, 30-day MACE occurred in one (0.09%, 95% CI: 0.002 – 0.5). Of all 1,547 patients, 60 patients had a MACE detected: 56 AMI during the initial attendance, four AMI post-discharge (one from ED, three after hospital admission). In total, of the 1,328 patients who did not have AMI during the target admission, and were followed-up, 30-day post-discharge MACE occurred in 4 (0.3%, 95% CI: 0.08 – 0.8).

Conclusion: The ADP supports safe, early discharge of low risk chest pain patients from the ED.

Key words:

Emergency department, chest pain, acute coronary syndrome, practice guideline, treatment outcome

Introduction

Patients with chest pain suggestive of acute coronary syndrome (ACS) make up 5-10% of Emergency Department (ED) presentations,¹ but most do not have an ACS.^{2,3} Since missing the diagnosis puts a patient at higher risk of subsequent AMI or other major adverse cardiac events (MACE),⁴ EDs traditionally use diagnostic pathways involving serial cardiac marker assays over periods of 6-24 hours.⁵⁻⁸

Since ED overcrowding adversely impacts on patient morbidity and mortality, measures to decrease ED length of stay (LOS) have been advocated.⁹⁻¹⁰ For chest pain, this includes the development of accelerated diagnostic pathways (ADP), based on simultaneous serial measurement of cardiac markers, such as cardiac troponin I (cTnI), CK-MB and myoglobin.¹¹⁻¹⁴ The use of point-of-care (POC) technology further reduces ED LOS.¹¹⁻¹⁷

In 2009, the Monash Emergency Medicine programme compared a traditional pathway of arrival and six-hour cTnI assays in the central hospital lab, with an ADP using an arrival and 90 minute POC assay of cTnI and myoglobin. A reduction in ED LOS of four hours for discharged patients and two hours for admitted patients was demonstrated.¹⁸ However, the POC tests were relatively expensive. In 2011, in order to maximize ED efficiency gains while limiting costs, Monash Emergency instituted a dual system for the routine assessment of chest pain patients. An ADP was introduced for patients felt at low likelihood of ACS or hospital admission, while the existing traditional pathway was continued for all other patients. Pathway choice was left as a subjective clinical decision, without a requirement for formal risk stratification scoring. After a period of general education, the system was introduced to all three Monash Health ED in August 2011, and has been in operation since.

Occurrence of MACE following ED discharge after ADP use for all chest pain patients during defined study periods is uncommon.^{11-12,15,17,18} At the time of this study, the incidence of MACE in a low risk population for whom an ADP is in routine use had not been described. The primary aim of this study was to establish the safety of the chest pain assessment system, by determining the 30-day MACE rate in patients discharged from the ED after assessment using the local ADP. Secondary aims were to describe 30-day MACE and other cardiac procedure rates for all patients assessed using the ADP, regardless of ED disposition. Patients assessed using the traditional pathway were not followed up, as the safety of similar traditional pathways has previously been demonstrated.¹⁹

Methods

Study design and setting:

A prospective cohort study was conducted on a consecutive sample of eligible patients at the three Monash Health EDs: Monash Medical Centre (tertiary referral, annual census 68,000 patients); Dandenong Hospital (urban district, annual census 57,000 patients); Casey Hospital (urban district, annual census 49,000 patients). The study was approved by the Monash Health Human Research and Ethics Committee and conducted in accordance with the STROBE statement for observational research.²⁰

Participants:

All patients aged 18 years and over, who were assessed using the ADP between June 6, 2013 and September 30, 2013, were included for follow-up.

Outcome measures:

Primary: incidence of MACE by 30 days from the target ED attendance, in patients who were discharged from the ED following assessment using the ADP.

Definitions for MACE^{11,15} are: death (not clearly non-cardiac), cardiac arrest, emergency revascularization procedure, cardiogenic shock, ventricular arrhythmia, high degree atrio-ventricular block, prevalent (at presentation) or incident (developing within 30 days) AMI.

Secondary: incidence of MACE and other cardiac procedures by 30 days for all patients assessed using the ADP. ADP negative patients subsequently diagnosed with MACE, and ADP positive patients with no apparent cardiac cause were reviewed.

Chest pain pathway and cardiac marker testing.

The Monash Chest Pain Assessment system is shown in Figure 1. Abnormal vital signs or ECG evidence of STEMI are the only defined exclusions for ADP use. The TIMI score is included as a prompt regarding possible risk. When an admission decision is made after two (or more) POC tests have been performed, as per the ADP, any subsequent cardiac marker tests are done in the central lab. Suggested disposition, based on defined cardiac marker cut-offs, is shown.

The three Monash Health EDs are all metropolitan, university associated, general hospitals. Shifts are supervised by an emergency physician from 08:00 to 24:00 each day, with a senior ED registrar being in charge overnight. Junior doctors are expected to seek senior advice on all patients, at an early stage, prior to initiating management plans. The choice of pathway is generally determined by senior ED doctors. Although POC cardiac marker testing can also be initiated by ED nurses, prior consultation is required with the doctor in charge. Every new doctor and nurse is orientated regarding risk stratification for chest pain patients, and the specifics of the pathways. This information is also readily available for reference on the Monash Health intranet. Patients having serial cardiac marker testing are all initially managed in the acute area of the ED. Following a first normal result, low risk patients being

assessed by the ADP are transferred to the ED Short Stay Unit. There are no separate Chest Pain Units at Monash Health hospitals. Disposition plans are all made in conjunction with the doctor in charge. If discharged, the patient may receive specific information pertaining to a non-cardiac discharge diagnosis, or may be referred for a cardiologist opinion on further investigation and management. This may be to a cardiologist they already regularly see, or to the Monash Heart Chest Pain Rapid Review Clinic. In the latter case, standard information about the general management of ischaemic chest pain, and reasons for return to the ED, is provided. The majority of referrals to this Clinic are seen within two weeks.

The POC device in routine clinical use is the AQT90 Flex immunoassay analyzer (Radiometer, Bronshøj, Denmark). For cTnI, lower and upper limits of detection are 10 and 25000 ng/L, the 99th centile value of the upper reference limit (URL) is 23 ng/L and the 10% coefficient of variation (CV) is at 40 ng/L. For myoglobin, lower and upper limits of detection are 20 and 900 ng/ml and the 99th centile value of the URL is 112 ng/ml. In the central hospital laboratory, the Beckman Coulter second-generation analyzer used the AccuTnI assay (Beckman Coulter Australia, Lane Cove West, NSW, Australia): lower limit of detection 10 ng/L, 99th centile value 40 ng/L and 10% CV at 60 ng/L. Average cardiac marker turnaround times for POC and central lab assays were previously found to be 18 and 77 minutes respectively.¹⁸ The POC device is located within the ED. Sample testing is bar code restricted to ED nurses who have been trained and accredited by the pathology department. Pathology staff perform daily quality control testing.

Study procedure:

Consecutive patients assessed for potential ACS were identified. The ADP group included those who had serial POC cardiac markers performed, and traditional pathway patients included non-ADP patients having serial central lab cTnI tests. Baseline information was drawn from the ED information system

(Symphony Version 2.30, Ascribe Ltd, Bolton, UK) and the patient's electronic medical record. At 30 days from the initial attendance, patient records were searched for subsequent MACE or other cardiac procedures. ADP patients who did not re-present were telephoned and questioned using a standardized interview format, to elicit occurrence of MACE or other cardiac procedures. Contact attempts were ceased after 60 days, at which time a final search of patient records was conducted. Patient contact was managed by one investigator (DG); study data were recorded in a secure database (Microsoft Access 2007, Microsoft Corporation, Mountain View, CA USA) by one investigator (RM).

Statistical analysis:

The study variables are presented as median with interquartile range or number and percentage as appropriate. MACE rates are reported as percentage with 95% confidence intervals (CI) and occurrence in different patient subgroups is described. Analyses were performed using Stata Version 8.0 statistical software (Stata Corporation, College Station, TX USA).

Sample size:

We assumed that the 30-day MACE rate in patients discharged from the ED would not exceed 2 per 1,000. This is the maximum incidence previously reported when an ADP was used to assess all chest pain patients.¹⁴⁻¹⁵ A sample of 1,000 discharged patients would yield an arguably acceptable MACE rate of 0.2% (95% CI: 0.03 – 0.66). To take in to account the likely admission rate, and to allow some margin for error, we aimed to include about 1,600 patients.

Results

During the 114 day study period 2,294 patients had serial cardiac marker testing for possible ACS. Of these, 1,547 (67.4%) had serial POC tests, as per the ADP; 747 (32.6%) had serial central lab cTnI tests, as per the traditional pathway. Baseline characteristics of the ADP and traditional pathway patients, and

for the total chest pain population prior to the introduction of the current system,¹⁸ are shown in Table

1. Median time between first and second POC assays was 105 minutes (IQR: 95 – 124), and between first and third assays, when performed, was 343.5 minutes (IQR: 244 – 382). Disposition, MACE and other cardiac procedures for ADP negative and positive patients are shown in Figures 2 and 3 respectively.

Of the 1,547 ADP patients, 1,286 (83.1%) were discharged from the ED; no follow-up information was obtained for 143 (11.1%). (Figures 2, 3) For all 1,143 discharged patients with follow-up information, MACE occurred by 30 days in one patient (0.09%, 95% CI: 0.002 – 0.5). This 58 year-old man was discharged with a diagnosis of gastro-oesophageal reflux disease. His POC cardiac markers and ECGs were normal. He returned on day 4 with an inferior STEMI. (Table 2)

Of all 1,547 ADP patients, no follow-up information was obtained for 163 (10.5%). Regardless of disposition, of the 1,384 patients with follow-up information, MACE occurred in 60 patients (4.3%, 95% CI: 3.3 – 5.5). These were: 56 (93.3%) with AMI during the target admission; the patient who returned post-ED discharge; and 3 patients with post-discharge AMI, after admission at the target attendance. (Table 2) Of these 60, nine (15.0%) occurred in the ADP negative group. These included three patients with post-discharge events, and six patients with late rises in central lab cTnI levels, which were performed following an admission decision. As no corresponding POC assays were measured, as per protocol, these were not considered to be false negatives for the ADP. Disposition, outcome and occurrence of elective cardiac procedures are shown for ADP negative and positive patients in Figures 2 and 3 respectively.

Baseline characteristics were similar between the 1,384 patients with follow-up information, and the 163 patients with none. (Table 3) With 1,286 patients being discharged from the ED, a maximum of three post-discharge MACE could be expected for our anticipated maximum rate of 0.2% not to have been exceeded (3/1,286, 0.2%, 95% CI: 0.05 – 0.7). Given that MACE occurred in one of 1,143 (0.09%) discharged patients with follow-up information, this maximum incidence would require an additional two MACE from the 143 (1.4%) patients without follow-up.

Limitations

Being largely subjective, selection of patients at low risk for ACS and hospital admission must vary between doctors. However, since the aim of the study was to assess the ‘real-life’ safety of the ADP, regardless of how patients were being chosen for it, this was not of concern, and findings are likely to be generalizable to other similar types of ED. No follow-up information was obtained for 10% of the patients, but the sensitivity analysis showed that MACE would need to occur at 15 times the rate in patients lost to follow-up (1.4% versus 0.09%) for the MACE rate to exceed our nominated acceptable maximum of 0.2%, with an upper 95% confidence limit of < 1%. This seems unlikely. Some MACE may not have been detected, due to patients being asked retrospectively about events. However, since MACE definitions are fairly objective and events are of a type which are likely to be remembered, this is likely to be minimal. No deaths were detected on registry search at six months, but long time frames for database updates limit the usefulness of this. This study was not designed to assess the diagnostic performance of the POC cardiac marker assays, and no comparisons with laboratory based biomarker results were made. The cardiac marker cut-offs and level of delta change used for diagnosis of AMI can be debated, but the definitions used here are those in use at Monash Health since 2011 and reflect our current clinical practice.

Discussion

This study demonstrates, in a 'real-life' setting, that the use of an ADP for the assessment of chest pain, in a selected, low-risk patient subgroup, facilitates early and safe discharge in routine practice. Of the 1,143 patients discharged from the ED after ADP use, there was a single (0.09%, 95% CI: 0.002 – 0.5) patient in whom a MACE occurred by 30 days. This finding is reassuring, since at the time of the study, there was no support for ADP by bodies such as the American Heart Association,⁵ the National Institute for Health and Care Excellence in the UK,⁶ or the National Heart Foundation in Australia,²¹ and this type of dual approach to chest pain assessment had not been described elsewhere.

The 30-day MACE rate in this study is generally consistent with that reported in previous research, where an ADP was applied to all chest pain patients for a defined study period.^{11-12,14-16} Goodacre¹² and Ng¹⁴ reported similar rates after ED discharge, of two from 2,243 (0.1%, 0.01 – 0.3) and one from 1,285 (0.1%, 0.002 – 0.4) patients respectively. 'Acceptable missed rates' for AMI have been debated,²² but a large clinician survey suggested a miss rate of < 1%.²³

The decision to adopt the dual approach for chest pain assessment at Monash Health, based on perceived risk, was largely economic. There have been suggestions that the added costs of POC systems to the ED can be off-set through other savings.^{18,24} However, a recent economic analysis by Goodacre in the UK concluded that the National Health Service was unlikely to view ADP with POC testing as being cost-effective.¹² Hence, our choice to restrict the higher cost system to the likely discharge subgroup, for whom ED LOS reductions have been shown to be greatest.^{11-12,13-16,18} The median ED LOS for the ADP population in this study was about five hours, versus 11.5 hours for the traditional pathway group.

With pathway choice having to be made early in a consultation, it was accepted that some ADP patients would ultimately prove not to be low-risk, and vice versa. For all chest pain patients, admission rates of 40-70%, and total MACE rates of 10-15%, are generally reported.^{13-14,18} The significantly lower admission and AMI rates in our ADP versus traditional pathway patients (17% versus 69% and 4% versus 32% respectively), suggest that low-risk patients were being selected quite well in day to day practice. Admission diagnoses for ADP patients with normal cardiac markers weren't formally recorded, but anecdotally, most did not relate to perceived ACS risk, but rather to concurrent problems such as atrial fibrillation, cardiac failure or airways disease, which had not responded as well as had been expected.

Recent studies have reported that patients who are defined as low-risk using formal risk stratification tools, such as EDACS,²⁵ TIMI,^{11,15,26} HEART,²⁷⁻²⁸ and m-Goldman scores,²⁹ have low subsequent MACE rates, and so are safe for early discharge when ADP negative. These groups are reported to comprise between 10 and 50% of all suspected ACS patients, but since pathway application has been theoretical in most studies, there is limited information on discharge rates in actual practice.^{11,15,25-29} Of particular interest was the ADAPT trial, where an ADP was tested but not used in practice.¹⁵ It was found that of 1,975 patients assessed for possible ACS, 392 (20%) were ADP negative (TIMI 0 with normal arrival and 2 hour cTnI levels).¹⁵ Of these 392, only one (0.25%) had 30 day MACE, so it was concluded that use of the ADAPT ADP would allow safe early discharge of pathway negative patients.¹⁵ A subsequent implementation study reported that 214 of 1,762 (19%) potential ACS patients were ADAPT ADP-negative, and appropriate for early discharge. Of these 214 patients, none had 30 day MACE.³⁰ Subsequently this ADP has been widely rolled out in Queensland.³¹ The 30-day MACE rate of 0.09% in this study, supports the safety of this alternative ADP. The ADAPT and Monash ADP are similar in their requirement for a history suggestive of possible ACS, haemodynamic stability and no suggestion of new ischaemia on ECG. The key difference is that for the ADAPT ADP to be negative, the cardiac markers

must be normal and the TIMI score must be 0; the Monash ADP only requires that the cardiac markers be normal. The TIMI 0 requirement restricts ADAPT ADP application to about 20% of the potential ACS population, of whom close to 100% are probably discharged; the Monash ADP was applied to 67% of the population, of whom 83% were discharged. While addition of a TIMI 0 component may aid consistency and reproducibility of ADP application, we demonstrated that the Monash system was no less safe. This suggests that use of TIMI 0 may be unnecessarily restrictive, and that other methods of risk stratification, in order to maximize usage without compromising safety, still requires further investigation.

Apparent false positive POC biomarker results were uncommon, and the three post-discharge MACE cases in ADP negative patients were not viewed as pathway failures. Two were correctly admitted as either unstable or new onset angina, and subsequent events were unavoidable. The one patient who returned with a STEMI after ED discharge, was erroneously diagnosed as reflux disease, rather than crescendo angina, so this was a failure of clinical interpretation and decision making.

In conclusion, when implemented into clinical practice, the selective direction of patients perceived to be at low risk for ACS and hospital admission, to assessment using an ADP, is a safe and effective approach to facilitate early discharge for those patients. Further research to validate these findings in different types of ED is required, and studies on the best biomarker type and cut-off values should be ongoing, as available assays and POC technology continue to evolve.

Competing interests

None declared.

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Table 1. Characteristics of patients assessed using the current ADP and traditional pathway, and all patients prior to the current system.¹⁸

	Current ADP patients (n = 1547)	Current traditional pathway patients (n = 747)	All patients, prior traditional pathway ¹⁸ (n = 671)
Age: median years (IQR) [†]	54 (43 – 67)	71 (57 – 81)	63 (55 – 71)
Males: n (%) [95% CI] [‡]	833 (53.9%) [51.3 – 56.4]	440 (58.9%) [55.3 – 62.5]	370 (55.1%) [51.3 – 58.9]
Admitted: n (%) [95% CI]	261 (16.9%) [15.0 – 18.8]	512 (68.5%) [65.1 – 71.9]	258 (38.5%) [34.8 – 42.2]
Prevalent AMI: n (%) [95% CI]	56 (3.6%) [2.7 – 4.7]	235 (31.5%) [28.1 – 34.9]	72 (10.7%) [8.5 – 13.3]
0, 90 and 360 min tests done: n (%) [95% CI]	62 (4.0%) [3.1 – 5.1]	59 (7.9%) [6.1 – 10.1]	75 (11.2%) [8.9 – 13.8]
ED length of stay: median minutes (IQR)	324 (234 – 483)	689 (490 – 1024)	580 [473 – 806]

† Interquartile range

‡ Confidence Interval

Table 2. Details of the patients with a post-discharge MACE.

	Presentation	Cardiac markers and ED disposition	Outcome
1	58 yo man: multiple bouts of typical pain, apparently similar to previous reflux pain. No cardiac risk factors. ECG normal.	Normal POC cTnI and myoglobin on arrival and after 114 min. Normal central lab cTnI on arrival. Discharged from ED as gastro-oesophageal reflux; also referred to cardiology outpatients.	Had ongoing intermittent pain post-discharge. Returned day 4 with worse pain. ECG showed inferior STEMI. Urgent angiogram: right coronary artery occlusion, stented. Central lab cTnI peak > 50,000 ng/L.
2	56 yo woman: atypical pain. No cardiac risk factors. ECG normal.	POC cTnI rose from 13 ng/L on arrival to 71 ng/L after 92 min. Admitted on this basis. Later central lab cTnI after 186 min and 458 min were 70 ng/L and 50 ng/L.	Discharged by cardiology next day as non-cardiac after normal CT coronary angiogram. Returned day 2 with more severe pain. Arrival and 6 hour central lab cTnI were 280 ng/L and 2570 ng/L. Angiogram next day showed ruptured plaque in distal vessel with wall motion abnormality consistent with NSTEMI.
3	74 yo man: typical pain, known diffuse coronary artery disease on recent angiogram. ECG unchanged.	POC cTnI and myoglobin normal on arrival and after 87 minutes. Admitted with diagnosis of unstable angina	Discharged on day 3 after medication adjustments. Returned day 6 with severe chest pain. Central lab cTnI peaked at 1900 ng/L. Repeat angiogram showed diffuse disease and inferior wall hypokinesis consistent with NSTEMI. Continued on medical management.
4	53 yo man: typical pain. Multiple cardiac risk factors but no history of heart disease. ECG normal.	POC cTnI and myoglobin normal on arrival and after 101 min. Central lab cTnI at 6 hours normal. Admitted under cardiology for CT coronary angiogram next day.	Self-discharged against advice and declined follow-up arrangements. Returned on day 12 with severe pain. Had dynamic ECG changes and cTnI peaked at 1700 ng/L. Angiogram on day 2 showed significant occlusions, two stents inserted.

Table 3. Characteristics of patients with and without follow-up information.

	Patients with follow-up (n = 1384)	No follow-up (n = 163)
Age: median years (IQR) †	54 (43 – 67)	52 (42 – 62)
Male sex: n (%) (95% CI) ‡	743 (53.7%) (51.0 – 56.3)	90 (55.2%) (47.2 – 63.0)
Admission: n (%) (95% CI)	241 (17.4%) (15.5 – 19.5)	20 (12.3%) (7.7 – 18.3)
0, 90 and 360 min tests done: n (%) (95% CI)	59 (4.3%) (3.3 – 5.5)	3 (1.8%) (0.4 – 5.3)

† Interquartile range

‡ Confidence Interval

Figure 1. Monash Chest Pain Assessment System.

Legend: ACS = Acute Coronary Syndrome; ADP = Accelerated Diagnostic Pathway; POC = Point of Care; TIMI = Thrombolysis in Myocardial Infarction

Figure 2. ADP negative patients: ED disposition and occurrence of MACE.

Figure 3. ADP positive patients: ED disposition and occurrence of MACE.

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