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Early atropine is safer than conventional atropine administration in the elderly undergoing dobutamine stress echocardiography

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Abstract

Background: Early injection of atropine during dobutamine stress echocardiography has been demonstrated in retrospective analyses to reduce the duration and dose of dobutamine infusion, while preserving a similar diagnostic accuracy with a lower incidence of adverse effects.

Aim: In our prospective study, we sought to explore the safety of the early atropine-dobutamine stress echocardiography protocol compared to the conventional protocol in elderly patients.

Methods: We enrolled 100 consecutive elderly patients who had been referred to our echocardiography laboratory for evaluation of myocardial ischemia. Once eligible, patients were randomly assigned to undergo either the conventional protocol (Group 1, 50 patients) or early atropine protocol (Group 2, 50 patients) where atropine was started at dobutamine infusion rate of 20 μg/kg/min if the heart rate was < 100 beats/min, and at 30 μg/kg/min if the heart rate was < 120 beats/min, (max 2.0 mg). Test duration and total dobutamine dose were calculated.

Results: The mean age of the whole study cohort was 69.8 ± 2.8 years, 54 (54%) being males. Patients in Group 1 received a higher total dose of dobutamine (15.7 ± 0.8 *vs* 12.2 ± 1.5 mg) and had a longer test duration (14.3 ± 3.5 *vs* 11.5 ± 1.3 min) as compared to Group 2 ($p < 0.01$ for both). The two groups received a similar total dose of atropine (NS). Group 1 patients had a higher incidence of ventricular extra-systoles, non-sustained ventricular tachycardia, atrial fibrillation, and hypotension.

Conclusions: In elderly patients undergoing dobutamine stress echocardiography, adopting the early atropine protocol offers a shorter test duration and a lower dobutamine dose, with consequently fewer adverse effects.

Key words: dobutamine stress echocardiography, atropine, safety, elderly

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INTRODUCTION

As a result of advanced treatment options, and the ensuing increase in life expectancy, diagnostic procedures for coronary artery disease (CAD) detection have been increasingly used in the elderly population. Due to the obvious limitations of exercise testing in elderly patients, dobutamine stress echocardiography (DSE) has become widely used in the evaluation of such patients [1]. Moreover, DSE has proven to be an accurate method of detecting CAD and predicting cardiac events in this patient population [2].

Dobutamine stress echocardiography is widely accepted for evaluating patients with known or suspected CAD, essentially because it is feasible, safe, and has a high diagnostic and prognostic accuracy [3]. However, failure to achieve target heart rate during DSE is associated with false negative results and limited sensitivity for detection of myocardial ischemia. In this sense, the addition of atropine to conventional DSE has offered promising diagnostic accuracy for unmasking myocardial ischemia, especially in patients receiving beta-blockers and those with mild CAD [4]. Furthermore, early

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injection of atropine during DSE has been demonstrated in retrospective analyses to reduce the duration and dose of dobutamine infusion, while at the same time preserving a similar diagnostic accuracy with fewer minor adverse effects [5, 6]. In our prospective study design, we sought to explore the safety of the early atropine-DSE (EA-DSE) protocol in achieving target heart rate compared to the conventional atropine-DSE (CA-DSE) protocol, in a series of elderly patients evaluated for CAD.

METHODS

Patient selection

We prospectively enrolled 100 consecutive elderly (above 60 years) patients referred to our stress echocardiography labs between October 2006 and May 2008. Patients were considered eligible for inclusion if they had ischemic-type chest pain or other symptoms suggestive of myocardial ischemia and were considered for evaluation by DSE. We excluded patients with unstable angina or myocardial infarction (MI) within the preceding four weeks, those with a protruding fresh left ventricular (LV) thrombus, those with significant valvular or congenital heart disease, or any myocardial disease apart from ischemia. We also excluded those with contraindications to dobutamine (for example, with a history of complex ventricular arrhythmias, or uncontrolled hypertension with blood pressure > 180/110 mm Hg), those with contraindications to atropine (for example, with a history of narrow-angle glaucoma, or obstructive uropathy) and patients with limited life expectancy due to coexistent disease (for example, malignancy). Before inclusion, informed written consent was obtained from each patient and the study protocol was reviewed and approved by our local institutional human research committee as it conforms to the ethical guidelines of the 1975 Declaration of Helsinki, as revised in 2002.

Definition of risk factors

The presence of hypertension was defined as systolic blood pressure ≥ 140 mm Hg and/or diastolic blood pressure ≥ 90 mm Hg, previously recorded by repeated non-invasive office measurements, which led to life-style modification or antihypertensive drug therapy. The presence of diabetes mellitus was defined as fasting plasma glucose ≥ 126 mg/dL, and/or two hour post-glucose load ≥ 200 mg/dL, or specific anti-diabetic drug therapy. Dyslipidemia was defined as LDL cholesterol > 100 mg/dL, and/or serum triglycerides > 150 mg/dL, and/or HDL cholesterol < 40 mg/dL (< 50 mg/dl in women).

Resting echocardiographic assessment

Assessment of regional and global LV systolic function was performed in all patients by trans-thoracic echocardiography using a Hewlett Packard Sonos 5500 cardiac ultrasound machine (Hewlett Packard, Andover, Massachusetts, USA) equipped with harmonic imaging capabilities. A 2.5 MHz phased array probe was used to obtain standard 2D, M-mode and doppler images. Patients were examined in the left lateral recumbent position using standard parasternal and apical views. Images were digitised in cine-loop format, and saved for subsequent playback and analysis. Views were analysed by a single echocardiographer employing the software program of the echocardiography machine. Regional wall motion was assessed according to the standard 16-segment model as recommended by the American Society of Echocardiography [7]. Regional wall motion was visually assessed for each segment individually, considering both endocardial excursion and systolic thickening, and each segment was graded according to the semi-quantitative scoring system described by Knudsen et al. [8]. Segments with poorly-defined endocardial borders for 50% or more of their length were considered non-visualised and assigned a score of 0 [9]. Wall thickening was assessed at a distance of at least 1 cm from the adjacent segment, to minimise the effect of tethering [10].

Dobutamine stress echocardiography protocols

Once eligible, patients were randomly assigned to undergo one or other of the following of two DSE protocols:

1. Conventional atropine-DSE protocol (50 patients)

Dobutamine (Dobutrex®, Eli Lilly and Company, Indianapolis, Indiana, USA) was administered by intravenous infusion starting at a dose of 5 μg/kg/min and raised incrementally every three minutes up to a maximum of 40 μg/kg/min, or until a study end-point was reached. In patients not achieving 85% of their age-predicted maximal heart rate at the end of the final stage, atropine was administered intravenously in 0.25 to 0.5 mg increments at one-minute intervals up to a maximum dose of 2.0 mg, while dobutamine infusion was continued.

2. Early atropine-DSE protocol (50 patients)

Dobutamine was administered as before, and atropine was started at dobutamine infusion rate of 20 μg/kg/min if the heart rate was still below 100 beats/min, and at dobutamine infusion rate of 30 μg/kg/min if the heart rate was still below 120 beats/min, being administered as before up to a maximum dose of 2.0 mg, while dobutamine infusion was continued.

Monitoring

All patients had continuous heart rate, electrocardiogram (ECG), and pulse oximetry monitoring. Heart rate and blood pressure readings were recorded at baseline, at the end of each stage of dobutamine infusion, and during recovery. A 12-lead ECG was recorded at baseline and during recovery. Patients were asked at the end of the test regarding any symptoms or adverse drug reactions. Test duration was calculated from the onset to the end of dobutamine infusion. The total dose of dobutamine administered in each test was also calculated.

Table 1. Baseline characteristics of the two individual study groups

	CA-DSE group (n = 50)	EA-DSE group (n = 50)	P value
Age (years)	69.7 ± 2.1	69.9 ± 3.5	NS
Males	24 (48)	30 (60)	NS
Diabetes	32 (64)	30 (60)	NS
Hypertension	35 (70)	38 (76)	NS
Smoking	10 (20)	10 (20)	NS
Dislipidemia	17 (34)	20 (40)	NS
Previous MI	0 (0)	2 (4)	NS
Previous PCI	1 (2)	4 (8)	NS
Beta-blocker use	10 (20)	20 (40)	< 0.01

MI — myocardial infarction; PCI — percutaneous coronary intervention; CA-DSE — conventional atropine-dobutamine stress echocardiography; EA-DSE — early atropine-dobutamine stress echocardiography

Test termination end-points

End-points for terminating the test included: attainment of the maximum dose of dobutamine and/or atropine; achievement of target heart rate (greater than 85% of age-predicted maximal heart rate); echocardiographic detection of wall motion abnormality not present at baseline or worsening of previously existing wall motion abnormality; symptoms judged to be unacceptable by the attending cardiologist; serious arrhythmia detected by ECG; ST segment elevation > 0.1 mV at 80 ms from the J point; systolic blood pressure > 200 mm Hg or diastolic blood pressure > 110 mm Hg or a decrease in systolic blood pressure > 30 mm Hg from the baseline [11].

Standard views were recorded at baseline, at the end of each stage of dobutamine infusion, as well as during recovery. Visual assessment of wall motion and systolic thickening was performed as before. The test was positive when wall motion abnormality not present at baseline, or worsening of previously existing wall motion abnormality, were detected.

Statistical analysis

All continuous variables are presented as mean ± standard deviation, if they were normally distributed. Differences in the normally distributed variables were assessed using the t-test and the paired t-test for dependent variables. Categorical variables were described with absolute and relative (percentage) frequencies. Comparisons between the two study groups were performed using the unpaired t-test (parametric) and Mann Whitney test (non-parametric) for continuous variables, and Pearson's χ^2 test or the Fisher exact test according to the expected cell count, for categorical variables. Twenty cases were randomly selected for analysis of intra-observer variability. Assessment of variability was performed using linear regression analysis. All tests were two-sided and a probability value of $p < 0.05$ was considered statistically significant. Analyses were performed with SPSS version 12.0 statistical package (SPSS Inc., Chicago, Illinois, USA).

RESULTS

Baseline clinical characteristics

A total of 100 consecutive elderly patients were prospectively enrolled in the current study, which comprises 50 patients randomly assigned to undergo the CA-DSE protocol, and 50 others randomly assigned to undergo the EA-DSE protocol. Table 1 shows the baseline clinical characteristics of the two groups. The mean age of the whole study cohort was 69.8 ± 2.8 years, 54 (54%) being males. The two groups were matched regarding age, gender, coronary risk factors, prior MI, and prior percutaneous coronary intervention. Nevertheless, more patients in the EA-DSE group were on beta-blocker therapy than those in the CA-DSE group [20 (40%) *vs* 10 (20%), $p < 0.01$].

Test protocol data

Patients from the CA-DSE group received a significantly higher total dose of dobutamine compared to the EA-DSE group (15.7 ± 0.8 *vs* 12.2 ± 1.5 mg, $p < 0.01$), and had a longer test duration (14.3 ± 3.5 *vs* 11.5 ± 1.3 min, $p < 0.01$). However, they received a similar total dose of atropine (0.43 ± 0.3 *vs* 0.46 ± 0.5 mg, NS). In the CA-DSE group, 47 (94%) patients achieved their age-predicted maximal heart rate, of whom three (6%) achieved it at a dobutamine infusion rate of 20 μg/kg/min, eight (16%) achieved it at a dobutamine infusion rate of 30 μg/kg/min, and the remaining 36 (72%) achieved it at a dobutamine infusion rate of 40 μg/kg/min. Meanwhile, in the EA-DSE group, all 50 patients achieved their age-predicted maximal heart rate, of whom 17 (34%) achieved it at a dobutamine infusion rate of 20 μg/kg/min, 21 (42%) achieved it at a dobutamine infusion rate of 30 μg/kg/min, and 12 (24%) achieved it at a dobutamine infusion rate of 40 μg/kg/min.

Hemodynamic data during test protocols

Table 2 shows hemodynamic data recorded during the two test protocols. Heart rate was similar between the two study

Table 2. Hemodynamic data of the two individual study groups at baseline and at peak heart rate

	CA-DSE group (n = 50)	FA-DSE group (n = 50)	P value
At baseline:			
SBP [mm Hg]	130 ± 22	135 ± 43	NS
DBP [mm Hg]	75 ± 12	80 ± 11	NS
Heart rate [bpm]	70 ± 12	71 ± 12	NS
At peak heart rate:			
SBP [mm Hg]	140 ± 30	145 ± 30	NS
DBP [mm Hg]	80 ± 15	85 ± 17	NS
Heart rate [bpm]	149 ± 20	154 ± 15	NS
% of maximal age-predicted heart rate	93 ± 13	95 ± 11	NS

SBP — systolic blood pressure; DBP — diastolic blood pressure; rest of abbreviations as in Table 2

groups, both at baseline and at the end of the protocol (NS for both). Similarly, the achieved percentage of age-predicted maximal heart rate at dobutamine infusion rate of 30 μg/kg/min, was similar between the two groups ($p > 0.05$, data not shown). Additionally, no statistically appreciable differences of systolic or diastolic blood pressure were found between the two protocols either at baseline or at dobutamine infusion rate of 40 μg/kg/min.

Safety of DSE protocols

The CA-DSE protocol was positive in 40 (80%) patients and negative in seven (14%). Three (6%) patients failed to achieve their target heart rate because the test was prematurely interrupted: one patient developed acute inferior MI, was admitted to the intensive care unit and received fibrinolytic therapy; the other two patients developed non-sustained ventricular tachycardia that stopped immediately after cessation of dobutamine infusion. The EA-DSE protocol was positive in 45 (90%) patients, and negative in only five (10%) patients, and no serious complications occurred. Reported complications from the two DSE test protocols are summarized in Table 3. Patients from the CA-DSE group had a higher incidence of ventricular extra-systoles, non-sustained ventricular tachycardia, atrial fibrillation and hypotension, while the EA-DSE patients had a higher incidence of hypertension. No cases of sustained ventricular tachycardia, ventricular fibrillation, syncope or death occurred in either group, during or immediately after the test.

Analysis of intra-observer variability revealed a close correlation between repeated measurements of regional wall motion by the single operator, with a correlation coefficient $r = 0.92$.

DISCUSSION

Currently, DSE is widely approved for detection of CAD [12––14], for risk stratification after MI [15], and for prediction of peri-operative and late cardiac events in patients scheduled for major surgery [16]. However, in addition to being time-consuming, DSE has often been limited by patient intolerance, chiefly related to drug adverse effects and test duration [17]. Furthermore, heart rate response might be inadequate in elderly patients and in patients receiving beta-blocker therapy [4, 18]. In this case, larger doses of dobutamine and longer test durations are needed, besides the addition of atropine to achieve the target heart rate [4, 19, 20]. In turn, this would further increase a patient's intolerance. We tested the hypothesis that early administration of atropine during DSE would reduce dobutamine dose and test duration, and consequently improve patient tolerance in the elderly population.

Consequences of early atropine administration

Our results demonstrated that early administration of atropine during DSE reduced dobutamine dose by 19.6% and test duration by 22.3%, ($p < 0.05$ for both). At the high infusion rate of dobutamine (40 μg/kg/min), heart rate was similar between the two study groups. However, the proportion of patients requiring this high infusion rate was reduced by 72.7% ($p < 0.05$). This was achieved without increasing the total dose of atropine given per patient (NS). Therefore, early atropine administration has decreased the fraction of 'patients with a blunted heart rate response' ultimately passing to the last stage of dobutamine infusion, yet without further increases of 'atropine load'. Furthermore, despite the fact that more patients undergoing the EA-DSE protocol were on beta-blocker therapy, the achieved percentage of age-predicted maximal heart rate at dobutamine infusion rate of 30 μg/kg/min was similar between the two groups ($p > 0.05$). This highlights the ability of early atropine to overcome the 'heart rate blunting effect' of beta-blockers in patients undergoing DSE [18].

Safety of early atropine administration

Although more patients in the EA-DSE protocol achieved a positive test result, far more complications occurred in patients undergoing the CA-DSE protocol. Moreover, in the CA-DSE protocol, three tests were terminated prematurely as a result of significant/serious complications, whilst in the EA-DSE protocol, no test was prematurely terminated. Even

Table 3. Adverse drug reactions of the two individual study groups

	CA-DSE group (n = 50)	EA-DSE group (n = 50)	P value
Arrhythmia:			
Atrial extrasystoles	12 (24)	3 (6)	< 0.001
Atrial fibrillation	2 (4)	0 (0)	< 0.05
Ventricular extrasystoles	17 (34)	4 (8)	< 0.001
Non-sustained VT	2 (4)	0 (0)	< 0.05
Sustained VT	0 (0)	0 (0)	—
Ventricular fibrillation	0 (0)	0 (0)	—
Bradycardia	0 (0)	0 (0)	—
Hypotension	4 (8)	1 (2)	< 0.05
Hypertension	8 (16)	11 (22)	NS
Myocardial infarction	1 (2)	0 (0)	NS
General:			
Chest pain	5 (10)	1 (2)	< 0.05
Headache	5 (10)	3 (6)	NS
Nausea	4 (8)	2 (4)	NS
Dry mouth	1 (2)	4 (8)	< 0.05
Flushing	2 (4)	4 (8)	NS
Urinary urgency	7 (14)	3 (6)	< 0.05

All variables are presented as numbers (percentage); VT — ventricular tachycardia

though the two groups received a similar total dose of atropine per patient, more arrhythmias occurred in the CA-DSE protocol. This suggests that dobutamine is more arrhythmogenic than atropine [11], a matter that deserves further exploration on a larger scale.

Comparison with other studies

Previous studies were able to demonstrate minor reductions in both dobutamine dose and test duration with the EA-DSE protocol as compared to the CA-DSE protocol (14% and 15% in the study by Tsutsui et al. [5], 10% and 7% in the study by Lessick et al. [11], 11% and 8% in the study by Lewandowski et al. [21], respectively) although they used higher total doses of atropine (90% more atropine in the study by Lewandowski et al. [21]) and eventually, they showed an almost similar rate of adverse effects. In comparison, our study has demonstrated an almost 20% reduction in dobutamine dose and 22% reduction in test duration, with no need for higher doses of atropine and with an obvious reduction in adverse effects. A recent randomised trial by Camarozano et al. [22] reported reductions in both dobutamine dose and test duration with the early atropine protocol with a similar atropine dose and a 'uniform' side effect profile. To the best of the authors' knowledge, only one report emphasised the safety of the early atropine protocol in the elderly population, and — in accordance with our results — showed a lower incidence of arrhythmias and hypotension compared to the conventional protocol [6]. Nevertheless, this report was based on retrospective analysis of registry data, with inherent selection bias.

The gold standard design for comparison between two protocols is the prospective, randomized, controlled one. Propensity-matched or adjusted retrospective comparisons, by definition, contain differences in group characteristics, since protocol choice was often dictated by measurable factors (vital signs and coexisting illnesses) and immeasurable factors (available expertise and preference of the attending physician). No adjustment, however meticulous, can correct for these multiple and often subtle differences. On the other hand, a well-designed prospective randomized, controlled study, through its design, obviates such a need. The prospective randomized nature of our study design would serve to further confirm and strengthen their results.

Finally, the fairly high rate of positive test results in the CA-DSE group (80%) is in agreement with the sensitivity rates reported in validated peer-reviewed articles in literature [23, 24] which described a sensitivity range of 74–86%. An even higher positivity rate with the EA-DSE protocol was observed in our study (90%). The higher positive response rate in the EA-DSE group can be explained by old age (69.9 ± 3.5 years) and the high prevalence of risk factors (60% diabetic, 76% hypertensive and 40% dyslipidemic) which reasonably account for a high prevalence of ischemic heart disease in this group.

Limitations of the study

Our findings are based on a single centre study with a relatively small sample size of the cohort, a fact that makes it difficult to generalise our results to all elderly patients undergoing DSE. Multi-centre studies using the same protocol and examining

a larger number of patients are needed. Moreover, the study population (100 patients) was composed of symptomatic patients referred for evaluation by stress echocardiography. This referral bias may further reduce the ability to extrapolate our results to elderly patients with asymptomatic CAD. Furthermore, test duration was calculated from the onset to the end of dobutamine infusion, excluding recovery time, which might be significant in some cases. However, being subjective in nature, it is difficult to delineate precisely the end of recovery time. Finally, the sensitivity, specificity, and diagnostic accuracy of the EA-DSE protocol was not validated against 'gold standard' evaluation by invasive coronary angiography, as this evaluation was outside the scope of our study.

Clinical implications

An increasing number of elderly patients with known or suspected CAD are currently being evaluated by DSE. The elderly population is much more susceptible to complications of DSE protocols, primarily due to adverse drug reactions (dobutamine and atropine). The performance of DSE with a significantly lower dose of dobutamine and a shorter test duration, at almost the same total dose of atropine, and with an essentially lower side-effect profile, would be an appealing option in this relatively 'fragile' patient category. All these advantages were clearly offered by the EA-DSE protocol, as shown in our study. Hence, at least from the 'safety' point of view, we can recommend that the EA-DSE protocol be the protocol of choice in elderly patients undergoing DSE evaluation for CAD.

CONCLUSIONS

In elderly patients undergoing DSE, adopting the EA-DSE protocol offers shorter test duration, lower dobutamine dose, and consequently fewer adverse effects.

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Wczesne podanie atropiny jest bezpieczniejsze niż konwencjonalne podanie atropiny podczas echokardiograficznej próby obciążeniowej z dobutaminą u starszych pacjentów

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Streszczenie

Wstęp: Wczesne podanie atropiny podczas echokardiograficznej próby obciążeniowej z dobutaminą w badaniach retrospektywnych wiązało się ze skróceniem czasu wlewu i zmniejszeniem dawki leku, przy podobnej dokładności diagnostycznej i mniejszej częstości działań niepożądanych.

Cel: Prospektywna ocena bezpieczeństwa protokołu dobutaminowej próby obciążeniowej z wczesnym podaniem atropiny w porównaniu z protokołem konwencjonalnym u starszych pacjentów.

Metody: Metodą prospektywną włączono do badania 100 kolejnych pacjentów w starszym wieku zakwalifikowanych w pracowni autorów do oceny niedokrwienia mięśnia sercowego. Chorych spełniających kryteria włączenia przydzielono następnie losowo do grupy protokołu konwencjonalnego (grupa 1, n = 50) lub do grupy badania z wczesnym zastosowaniem atropiny (grupa 2, n = 50), podczas którego atropinę podawano przy prędkości wlewu dobutaminy 20 μg/kg/min, jeśli częstość rytmu serca pozostawała mniejsza od 100/min lub przy prędkości 30 μg/kg/min, jeśli częstość rytmu była niższa niż 120/min (maks. 2,0 mg). Obliczono czas badania i całkowitą dawkę dobutaminy.

Wyniki: Średni wiek badanych wynosił 69,8 ± 2,8 roku, w grupie było 54 mężczyzn (54%). Chorzy z grupy 1 otrzymali wyższą całkowitą dawkę dobutaminy (15,7 ± 0,8 *v.* 12,2 ± 1,5 mg), a test trwał dłużej (14,3 ± 3,5 *v.* 11,5 ± 1,3 min) w porównaniu z grupą 2 ($p < 0,01$ dla obu porównań). W obu grupach dawka atropiny była podobna (p = NS). W grupie 1 częściej obserwowano przedwczesne pobudzenia komorowe, incydenty nieutrwalonego częstoskurczu komorowego, migotania przedsionków i hipotonii.

Wnioski: U starszych pacjentów poddawanych echokardiograficznej próbie obciążeniowej z dobutaminą protokół z wczesnym zastosowaniem atropiny pozwala na skrócenie czasu badania, zmniejszenie dawki dobutaminy i, w konsekwencji, zmniejszenie częstości działań niepożądanych.

Słowa kluczowe: echokardiograficzna próba obciążeniowa z dobutaminą, atropina, bezpieczeństwo, osoby starsze

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