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ABSTRACT

Objective: To ascertain the prevalence of erectile dysfunction (ED), how it is perceived and the percentage seeking treatment for the condition in a population of men with

- cardiovascular disease (CVD) attending a cardiac rehabilitation programme in East
- London, United Kingdom (UK).
- Participants: 100 male participants aged between 30 and 88 years attending a cardiac rehabilitation centre in East London.
- Methods: An audit of men attending a cardiac rehabilitation programme was conducted. Participants completed the International Index of Erectile Function (IIEF-5)
- to ascertain the severity of ED; adapted 'bother score' item from the International
- Prostate Symptom Score (IPSS) to investigate the extent to which participants were bothered by the symptoms of their ED and questions related to both ED treatment-
- seeking and beliefs about the impact of cardiac medication on ED. Demographic and
- clinical data were also collected. The audit was carried out between January and September 2014.
- **Results:** Out of 117 male participants, 100 were audited (85.5% uptake). Prevalence of ED in this cohort was 80% and 38% were suffering with moderate or severe ED. Older men had significantly higher levels of ED and participants with severe ED were significantly more bothered by their condition. Those of Asian or British Asian descent reported significantly higher levels of ED severity than men from white ethnic backgrounds. 65% of men with ED had never spoken to a healthcare professional (HCP)
- about the condition and 35% believed that their medication had a deleterious effect on erectile function.
- **Conclusion**: High incidences of ED remain undetected in this patient population. The study stresses the importance for HCPs to discuss ED with patients within primary care and cardiac rehabilitation programmes, which in turn could reduce mortality in those at
- risk of a future cardiac event, as well as facilitate access to ED treatment.

92

Key Words: Audit; cardiac rehabilitation; cardiovascular disease; erectile dysfunction;
 help seeking behaviour; prevalence.

95

96 **INTRODUCTION**

97 The term cardiovascular disease (CVD) refers to all diseases of the heart and circulatory 98 system and costs the NHS and the United Kingdom (UK) economy approximately £30.6 99 billion per year (Care Quality Commission. 2014) Coronary heart disease (CHD) is one 100 such disease and is the biggest single cause of death in the UK. For men, CHD is the most 101 common cause of premature death (mortality before 75 years of age) and was 102 responsible for over 15% (>17,000) of premature deaths in 2012 (Bhatnagar et al. 103 2015).

104

105 Erectile dysfunction (ED) is defined as a man's consistent or recurrent inability to attain and/or maintain a penile erection sufficient for sexual activity (Montorsi et al. 2010). 106 Prevalence rates of ED for individuals at risk of, or suffering with CVD are reported to be 107 108 as high as 75% (British Heart Foundation 2014; Dusing 2003). ED and CVD share similar 109 aetiologies and risk factors including; obesity, diabetes mellitus, physical inactivity, 110 hypertension, dyslipidaemia and tobacco usage (Ponholzer et al. 2005). ED is typically 111 experienced before the onset of a cardiac event and can be regarded as an early 112 indication of underlying CVD (Montorsi et al. 2003). Due to arteries in the penis being 113 approximately 1 - 2 mm compared to larger arteries such as coronary arteries (3 - 4)114 mm), they suffer obstruction by atheromatous plaque earlier (Jackson 2013). Therefore, 115 early diagnosis of ED can be a crucial indication of undetected CVD. The mean time 116 between developing ED and having a cardiovascular event, such as myocardial 117 infarction or cerebrovascular accident, is approximately three years (Montorsi et al. 118 2003).

119

120 Medication prescribed for CVD can cause further deleterious effects in relation to 121 erectile function (Nicolai et al. 2014). Side-effects of antihypertensive medications 122 (particularly beta-blockers and thiazide diuretics) can cause ED (Dusing 2005). As a 123 result, patients who experience ED as a side-effect can become non-adherent to such medication regimes (Doumas and Douma 2006). In a qualitative study involving a 124 125 cohort of 38 hypertensive patients, ED was reported as a reason for missing doses or for ceasing hypertensive medication to preserve erectile function, however, the authors do 126 not report which hypertensive medications patients were taking (Voils et al. 2008). A 127 recent systematic review provides support for the notion that both thiazide diuretics 128 129 and a majority of beta-blockers have a negative effect on erectile function, whilst the 130 beta-blocker Nebivolol, may have a positive effect. It is suggested that this is due to 131 nitric oxide-mediated vasodilatory properties, which improve endothelial function and 132 hence erectile function. In addition, it was concluded that there was no evidence to 133 suggest that; angiotensin-converting-enzyme (ACE) inhibitors, angiotensin-receptor-134 blockers (ARB's) and calcium-channel-blockers have a deleterious effect on erectile 135 function (Baumhakel et al. 2011).

136

In addition to pharmacological induced ED, patient perceptions are important when considering the effects of CVD medication on ED. Ninety-six men prescribed atenolol for CVD were split up into 3 groups; one group were blinded to the drug given, the second 140 were informed about the drug but not its side effects and the final group were informed 141 about the drug and its side effects, which included ED (Silvestri et al. 2003). ED was 142 reported in 3.1, 15.6 and 31.2% of the groups respectively. It was suggested that 143 knowledge and beliefs about the potential side effects of CVD medication may create 144 anxiety, which in turn, may have an effect on erectile function (Silvestri et al. 2003). An 145 alternative explanation could be that an awareness of the link between CVD medication 146 and ED may increase the reporting of erectile symptoms.

147

148 The International Prostate Symptom Score questionnaire (IPSS) includes an item which 149 is referred to as the 'bother score'. This item has previously been adapted and used in ED research (Steggall and Butler 2012). Steggall and Butler (2012) indicated that 150 regardless of ED severity, men who took part in their study were 'bothered' by their 151 152 condition and perceived their symptoms negatively. Despite this, help-seeking in relation to ED is problematic. Research indicates that less than 25% of men actively 153 seek treatment for ED (Laumann et al. 2009) and embarrassment is often reported as a 154 major reason for not wanting to discuss sexual health issues with a healthcare 155 156 professionals (HCP) (Byrne et al. 2013). Hackett recommends that in order to improve 157 detection, patients presenting in primary care with diabetes, obesity, depression or 158 cardiovascular disease should be asked whether they are experiencing ED (Hackett 159 2009).

160

161 This paper details an audit of a cardiac rehabilitation service in East London to ascertain
162 the prevalence of ED and whether it has been detected and/or treated. The audit aimed
163 to:

- 164 investigate the prevalence and severity of ED in a cohort of men attending a
- 165 community based cardiac rehabilitation service in East London using the
- 166 International Index for Erectile Function (IIEF-5) (Rosen et al. 1999)
- 167 identify the extent to which patients are bothered by their ED
- 168 identify what proportion of men with ED had sought treatment
- 169 identify whether men considered ED to be a side-effect of medication

170 **METHODS**

171 **Participants**

172 All men attending the cardiac rehabilitation programme were eligible for inclusion in

- 173 the audit.
- 174
- 175 **Procedure**

Permission to conduct the audit was obtained from the Assurance Department of East London NHS Foundation Trust (ELFT) and subsequently took place between January and September 2014. ELFT provides a cardiac rehabilitation programme across a variety of locations including both community and hospital based settings in East London. Men who were newly referred to the cardiac rehabilitation programme were given the audit questionnaire to complete when they arrived to participate in one of the cardiac rehabilitation sessions. Participants were informed that all questionnaire responses would be anonymous. In accordance with the Data Protection Act 1998 (Parliament 1998) all aspects of participants' data were treated with strict confidence. Each participant was assigned a unique identification number to ensure data were anonymised. Hard copies of questionnaires were stored within locked filing cabinets in a locked office on NHS premises, along with digital data which were stored on an NHS password protected network drive.

- 189
- 190 Materials

As part of standard care, participants completed a self-report questionnaire. Clinical and 191 192 demographic data were extracted from participants' medical records. Where participants could not speak English, a member of the Trusts health advocacy service 193 194 translated the questions and recorded participants' responses. The pack included the IIEF-5; a self-report questionnaire designed to detect the presence and severity of ED 195 (Rosen et al. 1999). It has been utilised successfully across a wide variety of studies, 196 translated into more than 30 languages and used extensively throughout the world 197 198 (Cappelleri and Rosen 2005). Each item of the IIEF-5 is scored on a five-point Likert 199 scale from; '1' least functional, to; '5' most functional. Possible overall scores range from 200 1 to 25; 21 and above is considered to indicate normal erectile function. Conversely, 201 lower overall scores represent poorer sexual function (See appendix; table 1) (Rhoden 202 et al. 2002).

203

The 'bother' question from the IPSS was re-worded for use with ED; 'If you were to spend the rest of your life with your erectile function just the way it is now, how would you feel about that?' Using a Likert scale, a score of 0 indicated being 'delighted', 1 'pleased', 2 'mostly satisfied', 3 'mixed', 4 'mostly dissatisfied', 5 'unhappy' and 6 'terrible.' This item has been used in men with ED (Steggall & Butler 2012) and is considered both valid and reliable (O'Leary 2005).

210

The audit also included the questions; 'Do you think any of your medications affect your erectile function?' and 'Have you ever told your doctor or nurse about your erectile

- 213 problems?' where participants answered either 'Yes' or 'No'.
- 214

215 Statistical Analysis

Data were analysed using IBM SPSS Statistics 21. To investigate the prevalence of ED, descriptive statistics were used for participant demographics and clinical data. Analysis of variance (ANOVA) and analysis of covariance (ANCOVA) were used to investigate differences between the five categories of ED severity on age and the subsequent degree of bother, as well as differences in ED severity in relation to ethnicity.

- 221
- 222 **RESULTS**

223 Demographic characteristics

Of the 117 men approached, 100 (85.5%) completed the audit. Participants who refused were widowed (n=2, 1.7%); had a wife who was not living in the country (n=3, 2.6%);

- did not complete the questionnaire or did not wish to participate (n=12, 10.25%). Ages
 ranged between 30 and 88 years with a mean age of 56.82 years (SD=10.48). A majority
 of the men were married (77%) and were non-smokers (72%). Patients were mainly
 Asian or British Asian i.e. Indian, Pakistani or Bangladeshi (n= 49, 49%) (See appendix;
 table 2).
- 231

232 Clinical characteristics

The majority of participants were attending cardiac rehabilitation as a result of a myocardial infarction (41%) or angina (31%). The most commonly prescribed medications were aspirin (97%) and statins (92%). The most prevalent comorbidities were hypertension (50.5%), hypercholesterolemia (48%) and type 2 diabetes (30%) (See appendix; table 3).

238 ED prevalence, severity and age

Of the 100 men who completed the IIEF-5, 80 (80%) suffered some degree of ED. The
self-reported mean duration of ED was 2.8 years (SD= 3.32 years) and the mean IIEF-5
score was 14.91 (SD= 6.5) (See appendix; table 4).

Moderate or severe ED was reported by 38 (38%) of men. An ANOVA indicated a significant difference in age between the five categorisations of ED severity; F (4, 95) = 6.59, p= 0.0001, partial eta squared = 0.22. The post hoc Tukey HSD test indicated that those with severe ED were significantly older than those with mild to moderate, mild and no ED (See appendix; table 5).

- 248
- 249 Bother score

Using the IPSS bother question to ascertain how participants felt about spending the rest of their lives with their current erectile function revealed that; 11 participants (11%) felt 'delighted', 15 participants (15%) were 'pleased', 1 (1%) was 'mostly satisfied', 26 (26%) had 'mixed' feelings, 18 (18%) felt 'mostly dissatisfied' or 'unhappy' (n=18, 18%) and 8 men (8%) reported that they felt 'terrible'.

255

An ANCOVA was used to explore differences between the 5 categorisations of ED severity and bother whilst controlling for the effects of age (See appendix; table 5). Results revealed a significant difference between groups on levels of bother F (4, 91) = 18.59, p < 0.01, partial eta squared = 0.45. Pairwise comparisons indicated that those with severe ED were significantly more bothered by their symptoms than those with all other ED severities including those with no ED. Those with mild, mild to moderate and mild ED were significantly more bothered by their symptoms than those with no ED.

263

Ethnic background was looked at in relation to ED severity (See appendix; table 6). ED severity was treated as a continuous variable as there were too few observations within some cells to perform a chi-squared test. An ANCOVA was utilized to look for any significant differences between ethnic groups in relation ED, whilst controlling for age. A significant difference existed between groups; F (3, 95) = 4.22, p = .008, partial eta squared = .117. Pairwise comparisons indicated that Asian or British Asian men scored significantly lower on the IIEF-5 than those from white ethnic backgrounds, therefore,
men of Asian or British Asian descent reported significantly higher levels of ED severity
than white men.

than white than white

274 ED severity and comorbidities

Of the 100 men who took part in the audit, 50 (50%) had hypertension, 30 (30%) had type II diabetes and 19 (19%) had both conditions (See appendix; table 7). Almost all men with diabetes had ED (29/30, 96.7%) and 80% had moderate or severe ED. In men with hypertension; 86% had ED and 46% had moderate to severe ED. All men with both diabetes and hypertension had at least mild ED and 84% had moderate or severe ED.

280

281 **Treatment seeking**

Of the 80 men with ED, 52 (65%) had never spoken to a HCP about their condition. Of those with moderate or severe ED, 52.6% had spoken to a HCP, while in those with less severe ED i.e. mild or mild to moderate severity; only 14.3% had done so. Of these men only one individual was receiving treatment for ED. Thirty five percent of men diagnosed with ED believed that medication was having an effect on their erectile function.

288 **DISCUSSION**

The prevalence of ED in this cohort of men attending a cardiac rehabilitation 289 programme was 80%, which is similar to that found in previous research (British Heart 290 Foundation 2014; Dusing 2003). Men with severe ED were significantly older and more 291 292 bothered by their symptoms. However, even those with mild ED reported feeling either 293 mostly 'dissatisfied' or 'terrible' about their erectile function, echoing the results of 294 Steggall and Butler's (2012) research which found that men with heart failure, 295 regardless of the severity of their ED, were bothered by the condition. The majority of 296 participants were Asian or British Asian, reflecting the composition of the local 297 community and these men were experiencing significantly more severe ED than men 298 from white ethnic backgrounds. The scope of this audit was not broad enough to 299 suggest reasons for this; therefore further research focussing on differences between 300 301 ethnic groups in relation to ED is needed.

Both ED and CVD share similar aetiologies and risk factors, including diabetes mellitus and hypertension (Ponholzer et al. 2005). The mean duration of ED in this cohort of men was 2.8 years, echoing the findings of Montorsi et al. (2003) who suggest that the mean time between developing ED and experiencing a cardiovascular event is approximately 3 years. In addition, this audit confirmed that men who were living with comorbid hypertension or type II diabetes were likely to report higher levels of ED severity.

309

A large proportion of men were prescribed beta-blockers, which have been reported as having negative effects on erectile function (Baumhakel et al. 2011;Nicolai et al. 2014).

312 Approximately one third of men believed that their medication impacted on their

erectile function. It is however, unclear whether it is the drugs themselves that may be causing this effect or beliefs and expectations men have about possible side effects, as demonstrated by Silvestri et al. (2003). Future research could address this important question by investigating men's beliefs about their CVD treatment in relation to ED, in order to examine whether such beliefs influence men's adherence to cardiac medication.

318

Despite 80% of the sample suffering with ED, 65% had not discussed their condition 319 320 with a HCP, reflecting the findings of Laumann et al. (2009) who suggest that less than 321 25% of men seek help for ED. Byrne et al 2013 suggests that this is due to 322 embarrassment with regard to discussing sexual health issues with HCPs. A limitation of this audit resides in the potentially embarrassing nature of ED and the format in which 323 participants completed the questionnaire. Cardiac rehabilitation classes are group 324 325 based. With this in mind, all efforts were made to safeguard participant's privacy when 326 completing the questionnaire; however, it is unlikely that feelings of embarrassment were completely eliminated. This could have been exacerbated in the small number of 327 328 participants that did not speak English who were read the questions aloud by a health 329 advocate. Although people who do not speak English are likely to have experience of 330 discussing their health with a health advocate, it would be prudent to keep this in mind 331 when considering the results to this audit.

332

333 The present audit, in line with previous research, highlights the important link between 334 CVD, diabetes, hypertension and comorbid ED (Ponholzer et al. 2005). Patients 335 presenting with such diseases offer an opportunity to enquire about and screen for ED. 336 Hackett (2009) suggests that HCPs need to assess ED effectively by asking the right 337 questions and demonstrate a willingness to take ED seriously as a medical condition. 338 The results of this audit suggest that this is still a serious obstacle preventing patients 339 obtaining necessary medical help. It highlights the need for ED to be adequately 340 addressed and screened for in order to detect CVD early and facilitate access to ED treatment. This could be achieved in primary care, but is also true of cardiology clinics 341 and cardiac rehabilitation programmes. If the profile of ED can be raised and the topic 342 addressed in various healthcare settings, then the possibility exists to reduce mortality 343 in those at risk of a future cardiac event, as well as increase quality of life in those 344 345 suffering with ED.

346

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- 349 rehabilitation staff for their support with this work.

350 **DISCLOSURES**

351 No competing interests to report.

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	What is already known about this subject? Cardiovascular disease (CVD) and erectile dysfunction (ED) share similar risk factors and aetiologies. It is estimated that the average time between first experiencing ED and suffering a cardiac event is approximately 3 years. As a result, ED is seen as an important early indication of CVD. Many men do not seek treatment for ED.
	What does this study add? Although the link between ED and CVD has been known for several years, this study found that ED is still going undiagnosed. Of those with moderate to severe ED symptoms, over half had not spoken to a HCP about their ED. Over one third of men with ED symptoms believed that their medication affected their erectile function. If HCPs ask men who are known to be at risk of or have CVD about erectile function, it could have important consequences for identifying CVD early as well as facilitating access to ED treatment.
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435

450 Appendix

Table 1: IIEF-5 points threshold

Threshold	Diagnosis
>21	Normal Erectile Function
17 – 21	Mild Erectile Dysfunction
12 – 16	Mild to Moderate Erectile
	Dysfunction
8 - 11	Moderate Erectile Dysfunction
1 – 7	Severe Erectile Dysfunction

Table 2: Participant Demographics

Characteristic	Respondents N (%)
Age:	r (/v)
≤ 30	1(1)
31 - 40	7 (7)
41 - 50	13 (13)
51 - 60	49 (49)
> 60	30 (30)
Total	100 (100)
Ethnicity:	
White British	25 (25)
White Irish	5 (5)
Any other white background	4 (4)
Asian or Asian British Indian	16 (16)
Asian or Asian British	15 (15)
Pakistani	
Asian or Asian British	18 (18)
Bangladeshi	
Any other Asian background	9 (9)
Black or Black British	1(1)
Caribbean	
Black or black British	1 (1)
Any other black background	1 (1)
Chinese	1 (1)
Any other ethnic background	4 (4)
Total	100 (100)
Relationship Status:	
Single	9 (9)
Married	77 (77)
Partner	6 (6)
Divorced	2 (2)
Separated	1(1)
Total	95 (95)
Smoking Status:	12 (12)
Smoker	13 (13)
Non-Smoker	/2 (/2)
Ex-Smoker	15 (15)
rotal	100(100)

455 456 Table 3: Participant Clinical Data

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Characteristic	Respondents N (%)
History of CVD Diagnoses:	
Myocardial infarction	41 (41)
Coronary artery disease	24 (24)
Angina	31 (31)
Heart failure	4 (4)
Dilated cardiomyopathy	1(1)
Ischemic heart disease	7 (7)
Heart valve disease	5 (5)
Arterial fibrillation	4 (4)
CVD Medication:	
Aspirin / Second anti-platelet /	97 (97)
Anticoagulants	
ACE Inhibitor / Angiotensin II	84 (84)
antagonist	
Beta Blocker	81 (81)
Statin	92 (92)
Glyceryl Trinitrate (GTN) spray	65 (65)
Calcium Channel Blocker	18 (18)
Potassium channel activator	5 (5)
Diuretics	24 (24)
Anti-arrhythmia drugs	2 (2)
Comorbidities:	
Hypertension	50 (50)
Type 2 diabetes	30 (30)
Hypercholesterolemia	48 (48)

47<u>8</u> Table 4: Participant responses by item on the IIEF-5, n(%)

How do you rate your	Very Low	Low	Moderate	High	Very High	Total
could get and keep an erection?	20(20)	20(20)	28(28)	22(22)	10(10)	100 (100)
When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never/ never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always/ always	
	23(23)	23(23)	18 (18)	17(17)	19(19)	100 (100)
During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered)	Almost never/ never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always/ always	
your partner?	21(21)	23(23)	19(19)	19(19)	18(18)	100 (100)
During sexual intercourse, how difficult was it to maintain your erection	Extrem ely Difficul t	Very difficult	Difficult	Slightly difficult	Not difficult	
to completion of sexual intercourse?	17(17)	19(19)	14(14)	21(21)	29(29)	100 (100)
When you attempted sexual intercourse, how often was it satisfactory for you?	Almost never/ never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always/ always	
,	21(21)	17(17)	19(19)	20(20)	23(23)	100 (100)

Table 5: Participants IIEF scores in relation to the bother score 491

ED and bother score as Indicated by IIEF-5 and IPSS Bother							
Question							
		Bother					
		score (IPSS	Age				
	n(%)	item)	M(SD)				
		M(SD)					
Severe ED	19 (19)	4.74 (1.28)	64.70 (10.86)				
Moderate ED	19 (19)	3.50 (1.42)	59.63 (7.23)				
Mild/Moderate ED	17 (17)	3.59 (1.18)	55.47 (8.72)				
Mild ED	25 (25)	2.79 (1.53)	54.96 (9.69)				
No ED	20 (20)	1.26 (1.76)	50.10 (10.21)				
Total	100 (100)						

493

494 Table 6: Ethnic group and ED severity 495

Ethnicity	Severe	Moderate
	ED	ED
	n (%)	n (%)
White English	4 (21)	3 (15.8)
White Irish	1 (5.3)	1 (5.3)
Other white	0	0
background		
Black or black British	0	0
Black or black British	0	1 (5.3)
Caribbean		
Any other black	0	0
background		
Asian an Asian Duitish		0

Total	19 (19)	19 (19)	17 (17)	25 (25)	20 (20)	100 (100)	_
Any otner etnnic background	U	2 (10.5)	U	1 (4)	1(5)	4 (4)	
Chinese	1 (5.3)	0 2 (10 F)	0	0	0 1 (5)	1(1)	
background	1 (3.3)	7 (21.1)	1 (3.7)	5 (12)	U) ())	
Bangladeshi Any other Asian	1 (5 3)	A (21 1)	1 (5 9)	3 (12)	0	9 (9)	
Pakistani Asian or Asian British	3 (15.7)	6 (31.6)	3 (17.6)	4 (16)	2 (10)	18 (18)	
Asian or Asian British	4 (21)	2 (10.5)	5 (29.4)	3 (12)	1 (5)	15 (15)	
Asian or Asian British	5 (26.3)	0	4 (23.5)	5 (20)	2 (10)	16 (16)	
Caribbean Any other black	0	0	0	0	1 (5)	1 (1)	
Black or black British Black or black British	0 0	0 1 (5.3)	0 0	0 0	1 (5) 0	1 (1) 1 (1)	
background	0	0	1 (5.9)	0	3 (15)	4 (4)	
White Irish	1 (5.3)	1 (5.3)	0	2 (8)	1(5)	5 (5)	
White English	4 (21)	3 (15.8)	3 (17.6)	7 (28)	8 (40)	25 (25)	

Mild/Moderate

ED

n (%)

Mild ED

n (%)

No ED

n (%)

Total

n (%)

496

497

498

499

500

501

Table 7: ED severity, type II diabetes and hypertension

	Total number of participants by category n (%)	Participants with type II diabetes mellitus n (%)	Participants with hypertension n (%)	Participants with both hypertension and type II diabetes mellitus n (%)
Severe ED	19 (19)	13 (43.4)	14 (28)	11 (57.9)
Moderate ED	19 (19)	11 (36.7)	9 (18)	5 (26.3)
Mild/Moderate ED	17 (17)	2 (6.6)	9 (18)	1 (5.3)
Mild ED	25 (25)	3 (10)	11 (22)	2 (10.5)
No ED	20 (20)	1 (3.3)	7 (14)	0(0)
Totals	100 (100)	30 (100)	50 (100)	19 (100)