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Direct to consumer advertising of robotic heart bypass surgery

Effectiveness, patient satisfaction and clinical outcomes

AQ: au

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Received 5 May 2015
Revised 10 January 2016
5 July 2016
13 August 2016
Accepted 15 August 2016

Abstract

Purpose – Robotic coronary artery bypass (rCABG) is a relatively novel and less invasive form of surgery. A yearlong direct-to-consumer advertising (DTCA) campaign was initiated to provide the community with information regarding rCABG, increase awareness and recruit patients. To optimize information content and ensure appropriate messaging for future campaigns, the authors analyzed the campaign effectiveness and compared service quality perceptions and clinical outcomes, following surgery across DTCA-responder and control groups.

AQ: 1

Design/methodology/approach – The institution initiated an rCABG program and one-year DTCA campaign. The authors prospectively documented all rCABG referrals prompted by these ads (DTCA-responder group) and concurrent referrals from medical providers (controls). Groups were compared according to baseline characteristics, perioperative outcomes, patient satisfaction (HCAHPS survey) and functional capacity at three weeks (Duke Activity Status Index). At six months, both groups were surveyed for patient satisfaction and unmet expectations.

Findings – There were 103 DTCA responders and 77 controls. The subset of responders that underwent rCABG ($n = 54$) had similar characteristics to controls, except they were younger, less likely to have lung disease or to be scheduled as an urgent case. Both groups had similar 30-day clinical outcomes, functional capacity recovery and overall satisfaction at three weeks. Follow-up interviews at six months and four years revealed that the DTCA group reported more unmet expectations regarding the "size of the skin incisions" and "recovery time" but no concern about "expertise of their surgeon".

International Journal of Pharmaceutical and Healthcare Marketing
Vol. 10 No. 4, 2016
p. 000

1750-6123
DOI 10.1108/IJPHM-05-2015-0016

Practical implications – The DTCA campaign was effective at recruiting patients. The specific focus of the ads and narrow timeframe for decision-making about CABG lends confidence that the incremental cases seen during the campaign were prompted primarily by DTCA. However, differences in unmet expectations underscore the need to better understand the impact of message content on patients recruited via DTCA campaigns.

Originality/value – This is one of the first studies to provide real-world direct empirical evidence of patients' clinical and attitudinal outcomes for DTCA campaigns. Furthermore, the findings contradict prevailing beliefs that DTCA is ineffective for prompting surgical referrals.

Keywords Satisfaction, Expectations, Robotic, Coronary artery bypass grafting, Direct to consumer, Minimally invasive surgery

Paper type Research paper

Introduction

The past 15 years have seen a dramatic growth in US direct-to-consumer advertising (DTCA) expenditures in health care. Despite this, DTCA remains an under-studied phenomenon of critical importance in pharmaceutical and healthcare marketing. This is emphasized in the "call for papers" of this special issue of the journal:

> Empirical research on the effect of DTCA is especially scarce. Much of the extant research on DTCA is exploratory in nature, mostly based on literature reviews and using content analysis as the methodology. Comprehensive and empirically validated models of consumer responses to DTCA are still rare in the literature and little is known about its effects on the attitudes and behavior of concerned parties.

To date, DTCA research has primarily been focused on the practice of prescribing drugs (DeLorme *et al.*, 2010) and has less frequently examined the impact of DTCA on patient satisfaction or actual clinical outcomes (Gilbody *et al.*, 2005). In the past decade, health care spending on DTCA for non-pharmaceuticals has increased nearly two-fold faster than all other forms of promotion (Liang and Mackey, 2011). For instance, the average US hospital now spends $1.3m/year on advertising, and this is the fastest growing form of DTCA (Schenker *et al.*, 2014). Much of this investment is used to promote their high-risk services that are profitable, such as surgical robotics (Jin *et al.*, 2011; Mirkin *et al.*, 2012) or oncology (Vater *et al.*, 2014). Advertising claims made by not-for-profit hospitals about physician services are only subjected to the ethical guidelines of medical and surgical societies (AMA opinion 5.02[1]; STS advertising policy[2]) and not regulation by either the FDA or Federal Trade Commission (Schenker *et al.*, 2014). As a result, this form of advertising is felt to live at the "margins of what is ethical".

The purpose of this article is to examine the marketing efficacy of DTCA and its potential impact on the patient–physician relationship using real-world direct empirical evidence. In March 2008, our institution initiated the first robotic coronary artery bypass surgery (rCABG) program in Massachusetts. This was followed four months later by a mass media DTCA campaign using television, radio, newspaper and billboards. Our study provides novel insights into:

- the ability of DTCA to influence patient decisions about discrete therapies and to drive patient recruiting; and
- the incidental influence of DTCA on clinical outcomes and patient satisfaction.

We also advance DTCA research by examining different types of DTCA communication messages (i.e. direct patient recruiting) (Nikki Lee-Wingate and Xie, 2010) used in a novel medical context (i.e. cardiac surgery).

Background

Coronary artery bypass grafting (CABG) is one of the most commonly performed and thoroughly studied surgical procedures in the medical field. Classically, this surgical procedure is performed via a highly morbid incision (i.e. a saw is used to divide the sternal bone in the midline of the chest). There are alternative interventions to treat coronary artery disease such as percutaneous coronary intervention (PCI) using balloon angioplasty and/or placement of a coronary artery stent that are less invasive. Because patients prefer less invasiveness (Pitter, 2014), they are usually referred for CABG only AQ: 2 if they meet specific indications and they are not candidates for PCI. Similar to PCI, a robotic operation enables coronary artery disease to be treated less invasively via small incisions in between the ribs that spare the sternal bone. rCABG has been shown to reduce invasiveness and postoperative complications compared to the open chest option (Cavallaro *et al.*, 2015; Whellan *et al.*, 2016). In contrast to PCI and CABG via sternotomy, rCABG is technically complex and has not been widely adopted outside of a few expert centers. A recent analysis showed that <1 per cent of annual CABG volume is done using the rCABG approach (Whellan *et al.*, 2016). In the context of a CABG market that is one of the most highly competitive in all of medicine, the failure to achieve safe and wide-spread adoption has plagued rCABG with controversy from its early beginning (King, 1999) until currently (Dhawan *et al.*, 2012).

Most cases of coronary artery disease involve preference-sensitive choices between viable options. Typically, a patient is first referred for CABG, discusses available options with the surgeon and finally an elective operation is scheduled over a timeframe ranging between one and three weeks. This typically provides an adequate window for the patients themselves to participate in the decision about where care is received. However, the vast majority accept the advice of their provider about where to have CABG and rarely investigate options on their own (Wilson *et al.*, 2007). Legally, informed consent must "entail an opportunity to evaluate knowledgeably the options available" (Cantebury and Spense, 1972). Consistently, patients have shown strong preferences toward less invasive options (Blue Cross Blue Shield of Massachusetts, 2007; Boden and Diamond, 2008). Yet, it has been uncommon for centers that only offer traditional surgery to disclose robotic surgery as an option (Scherr *et al.*, 2016). This lack of disclosure about less invasive options may result, because its proposed advantages are less meaningful to physicians than their patients (Cooper *et al.*, 2014). An explosive growth of health information has created a shift in consumer sophistication and a platform for hospitals to articulate their most attractive innovations directly to potential patients (Larson *et al.*, 2005). DTCA is one strategy that seems favorably positioned to leverage the latent patients' desire for information about less invasive procedures such as rCABG, raise patient awareness for this surgical procedure and recruit new patients for the medical centers where it is performed.

Previous research on DTCA of hospital services has shown that most physicians believe that DTCA motivates patients to seek specific treatments and also changes their expectations of their doctors (Robinson *et al.*, 2004). However, the same research also demonstrates that few patients believe that DTCA motivates them to seek a specific

type of care or changes their expectations *vis-à-vis* their doctors. Although there appears to be a wide perceptual chasm on how the two sides of the patient–physician dyad perceive the impact of DTCA, both sides agree that DTCA does not provide enough information on treatment options. Notwithstanding the general merits of these types of self-reported opinion surveys, it is also important to consider direct evidence based on actual clinical data to truly understand DTCA's effectiveness and its impact on patient satisfaction and expectations.

The intent of the DTCA campaign concerning rCABG was to highlight the advantages of this novel procedure to potential patient candidates and health-care providers while maintaining realistic expectations regarding outcomes related to the procedure. In this context, our research objectives were to evaluate the overall DTCA campaign efficacy based on the number of referrals caused by the campaign relative to the estimated number of potentially appropriate candidates in the market. In addition, we investigated how well the DTCA campaign communicated claims that were relevant and accurate as evidenced by a variety of outcomes such as patient satisfaction.

Based on previous research, we expected that DTCA carried with it a risk of distorting patient expectations (Gilbody *et al.*, 2005) and that those expectations would play a critical role in determining patient satisfaction with a treatment (Zeithaml *et al.*, 1990). Drivers of satisfaction and consumers' perceptions of service quality have been well described in the SERVQUAL model (Parasuraman *et al.*, 1985), which has been successfully applied to studying service quality in many service settings, including health-care delivery. Using the assumption that "quality" from the standpoint of the consumer is generally driven by the difference between his/her service expectations and his/her perceptual assessments of the service outcomes, SERQUAL identifies five discrete gaps in the service delivery chain. These gaps arise from differences in:

(1) consumer expectations and the provider's perception of those expectations (empathy);

(2) provider perceptions of consumer expectations and actual service quality specifications (reliability);

(3) service quality specifications and delivery (technical quality);

(4) external communications (e.g. advertisements) about the service and actual service delivery (honesty); and

(5) expectations and actual perceptions of the service (functional quality) (Parasuraman *et al.*, 1985).

In this field-experiment setting, we were able to compare outcomes and unmet expectations among patients who responded to the ads (DTCA responders) to those of a control group referred via routes that are traditional for a cardiac surgical practice (e.g. cardiologist referral, word of mouth, etc.). Because we could expect (and/or statistically control) that DTCA responders and controls would have similar clinical experiences (same surgeon and hospital), we theorized that any satisfaction difference between the two patient groups should be explained by differences in their expectations and/or motivation to be critical of their outcome. The hypothesis of this study was that the process of responding to DTCA creates higher expectations, and greater tendency should be dissatisfied with rCABG than controls.

Methods

In July 2008, our institution initiated a DTCA campaign regarding its rCABG program, the first and only one in Massachusetts at that time, using a variety of media outlets, including television, radio, newspaper and roadside billboards. Each ad provided the address of our website with further program details and contact information (i.e. the personal e-mail address of the lead surgeon and office phone number). An example of the TV ad is available online[3]. Health-care marketing campaigns were common in Boston (Rowland, 2006), particularly for profitable services such as cardiac surgery (Resnick *et al.*, 2005). Most ads aimed to build an image and reputation and not drive patients toward specific procedures. The campaign by our institution was unique in its clear goal to influence patient decisions about a discrete therapy.

Patient selection

Between July 2008 and July 2009, all patients contacting the cardiac surgery office to request an appointment to discuss rCABG were logged into a prospectively collected database that included information about whether patients learned about our program through DTCA. An established relationship existed between the cardiac surgeon and referring cardiologist in virtually every case prior to our DTCA campaign and for all control patients in the study. This made it straightforward to screen for those patients that contacted our office and whose cardiologist had no prior referral relationship to our group. We confirmed in 103 patients that the marketing campaign triggered their consultation ("DTCA responders") after contacting their primary care providers and/or cardiologists. A subgroup of 54 DTCA responders was appropriate for rCABG and underwent this procedure at our institution. All other rCABG cases during the study period were confirmed to have been referred via traditional means and *not because of DTCA* (controls, $n = 77$). Complete clinical data were available for all the controls, but only 43 DTCA responders; 11 were from outside Massachusetts and did not return for 30-day follow-up and were excluded.

The inclusion criteria were all patients presenting to Boston Medical Center during the study timeframe that had been diagnosed by their cardiologist with severe coronary artery disease that met standard indications for surgical revascularization (Hillis *et al.*, 2011), and their coronary targets were deemed suitable for grafting via a robotic approach. Patients were excluded from the study if they did not have an indication for CABG, their coronary artery blockages were unable to be completely revascularized or they were contraindicated for less invasive surgery (e.g. unstable blood pressure, severe pulmonary disease or decompensated heart failure). Patients with no valid contact information or did not return for post-operative follow-up were also excluded. Study patients were assigned to the DTCA group if they were "self-referred", and their cardiologists did not refer them for the robotic option. The remainder were told about robotics by their cardiologist and stated that DTCA did not lead them to the option of rCABG. These patients were assigned as controls.

Written informed consent for anonymous data collection and analysis of all patients was obtained before the operation. The local institutional review board (IRB) approved the study and waived the need for additional patient consent.

Surgical procedure

Patients in the DTCA and control groups were all treated with the identical surgical approach – rCABG – as described per the protocol used by our group provided elsewhere (Poston *et al.*, 2008) and illustrated in a video posted online[4]. Any differences in therapy were due to individual differences in specific coronary anatomy, operative risk factors and co-morbid disease. In appropriate patients, a hybrid strategy was used with PCI performed in a separate setting using drug-eluting stents where aspirin and clopidogrel were given prior to PCI (300 mg, followed by 75 mg daily thereafter). Long-term success of this new procedure was determined by phone interview with each patient at four years after surgery to determine freedom from the need for repeat coronary revascularization or recurrent angina (chest pain related to the heart).

Study population characteristics

Background demographic and clinical information was gathered from the clinical records. Demographic information included age, sex, race, marital status and level of formal education. Clinical information included relevant medical history, comorbid conditions, laboratory information and medication profile. Patients without clinical follow-up were excluded from the study, leaving 43 patients in the DTCA group. Patient satisfaction surveys (i.e. HCAHPS) were returned at three weeks from 61 per cent of the DTCA cohort and 63 per cent of controls. The collection of these data by the hospital was restricted by protocols designed to satisfy federal requirements for the uniform measurement of patient satisfaction, which constrains attempts to increase the response rate[5].

Outcomes of interest

Outcomes of interest during the study included the following:

Clinical outcomes and patient satisfaction antecedents. Each group was assessed for factors expected to influence patient satisfaction:

- demographical information, including level education and marital status;
- the incidence of major complications at 30 days;
- perceptions of pain control during hospitalization; and
- recovery of physical function at three weeks.

The level of education and marital status was obtained from each rCABG patient by phone interview. The incidence of major complications during the first 30 days post-surgery (i.e. mortality, permanent stroke, deep sternal infection, reoperation for bleeding, renal failure and intubation for longer than 24 h) was obtained from the Society of Thoracic Surgeons National Database. Pain control was defined by patient response to Question #13 on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey mailed approximately three weeks after discharge[6]. Specifically, we monitored the percentage of patients answering "always" to the question: "how often pain was well controlled?". Recovery of physical functioning was assessed at three weeks after discharge using the Duke Activity Status Index (DASI) questionnaire. The DASI is a brief, standardized, self-administered questionnaire administered via mail that gauges the patient's ability to perform common activities and

provides a weighted score (range: 0-58.2) that assesses overall functional capacity (Hlatky *et al.*, 1989).

Study subjects were again contacted by phone at four years after surgery and asked the following questions:

- Have the doctors performed any other intervention on your heart since your original surgery, including repeat surgery or another angioplasty/stent procedure?
- Have you had any recurrent angina (chest pain related to the heart) since the original surgery?

To minimize response bias, the surveys were confidential, with only a non-surgeon reviewer having access to the identifying patient information.

Direct-to-consumer advertising effectiveness. DTCA penetration was defined as the number of inquiries about the ad to our office divided by the estimated target population for the ad. The typical target population for rCABG is patients referred for surgical revascularization that require only one or two bypass grafts to completely address all the blocked coronary arteries. Patients requiring bypass of a more extensive number of blockages require a conventional (i.e. sternotomy) approach and are not usually suitable for rCABG. The number of patients who underwent CABG at any Massachusetts hospital using either one or two coronary bypass grafts during the study period (n = 934) was available from the state's publicly reported CABG database: Massachusetts Data Analysis Center-Cardiac Surgery and Percutaneous Coronary Intervention[7]. This information defined our target population. Because of the scope of the study, carry-over effects of DTCA (e.g. r-CABG cases done after the campaign) were not considered or measured for this analysis.

Patient satisfaction outcome. The primary endpoint of this study was patient satisfaction, as defined by a comparison of perceptions vs expectations of rCABG. A custom survey (see below), performed by phone interview, was obtained at six months. The survey instrument consisted of questions that assessed the three claims about rCABG made in each of the mass media ads (other than billboards): quick recovery, small incisions and the expertise of the surgeon. At the six-month interview, each patient was asked about their actual perceptions compared to what they expected prior to surgery. The results were categorized using a Likert (1-5) scale. A response of 2 ("less than expected") or 1 ("far less than expected") was categorized as "unmet expectation" according to prior criteria (Freilich *et al.*, 2010).

To evaluate for potential characteristics associated with unmet expectations, *post hoc* subgroup analysis comparing baseline characteristics and clinical outcomes of patients with unmet expectations to the rest of the cohort was also performed.

As a control for unmet expectations, more generalized patient satisfaction with the hospital and staff was determined using the HCAHPS survey at approximately three weeks after discharge. This was performed by mail, with surveys returned from 61 per cent of the study cohort and 63 per cent of controls. A raw composite satisfaction score was generated on a Likert scale from answers to the first 25 questions of the survey and then converted to an interval (1-100) scale to obtain an overall score as per HCAHPS protocol. A sample of the survey is available online[8].

Statistical analysis

The primary outcome of comparison between the two groups was length of hospital stay as a surrogate for recovery time and self-efficacy (Hall and Dornan, 1990). Univariate linear regression was used to adjust for potential confounders (independent variables) on length of hospital stay (dependent variable). Potential confounders determined *a priori* included age, sex and baseline clinical comorbidities found to be significantly different between groups (e.g. pre-existing chronic lung disease). We also performed a *post hoc* comparison of patients with all expectations satisfied compared to those that reported unmet expectations. These analyses were performed using the Fisher's exact and Student's *t*-test for categorical and continuous variables, respectively. Continuous variables were subjected to a Komogorov–Smirov test for normality. Non-normally distributed data were subjected to the Mann–Whitney U test for continuous variables. Statistical significance was set a p-level of 0.05. All analyses were performed using IBM SPSS Statistics 21.

Results

Study population characteristics

During the 12-month study period (July 2008-July 2009), a total of 103 potential patients, or their representatives, contacted our office as a consequence of the DTCA campaign for a "second opinion" consultation. After this consultation, 71 were found to be appropriate candidates for rCABG (i.e. DTCA responders). Out of these candidates, 54 (76 per cent) went on to have rCABG surgery, 2 (3 per cent) underwent non-robotic procedures and 15 (21 per cent) chose to not have surgery at our institution. During the study period, an additional 77 patients were referred by traditional means and underwent rCABG at our institution. These patients were enrolled into the control group.

Clinical follow-up at 30 days was complete in controls (77 out of 77 patients) but incomplete in the DTCA cohort (43 out of 54 patients). A lower proportion of DTCA patients lived within the primary service area of the hospital (13 vs 74 per cent), which likely increased the difficulty of returning to our office for clinical follow-up (Table I). **T1** Surveys at six months and four years were obtained from all but one of the eligible study patients (one control patient lost to follow-up). **AQ:3,AQ:4**

DTCA responders who underwent this procedure were younger, less likely to have lung disease and more likely to be scheduled as an elective case when compared to controls (Table I).

Clinical outcomes and patient satisfaction antecedents

Comparing the early clinical results for the DTCA responder and control groups, there were no differences in the lengths of time on the ventilator or in the intensive care unit (Table II). Mean total hospital stay (dependent variable) was less in the DTCA group (5.9 vs 7.9 days, $p = 0.011$, $F = -2.321$) but did not remain significant after adjusting for age, sex and preoperative comorbidities (independent variables) in a linear regression model (6.3 vs 7.8 days, $p = 0.072$, $R = 0.244$). At three weeks, there were no significant differences in the degree of activity tolerance between groups when expressed in absolute value (DASI scores: 21.8 vs 21.2 out of 58.2, Table II). At four-year follow-up, there were two patients in each group that had required repeat revascularization **T2;AQ:5**

because of failure of a bypass graft (96.4 vs 97.5 per cent freedom from revascularization, $p = 1.00$).

Direct-to-consumer advertising effectiveness

The DTCA campaign generated 71 qualified leads out of a potential market of 934 CABG cases involving one or two bypass grafts that were performed in the local region during the study period (i.e. 7.6 per cent potential share of the market). There were 54 leads that were converted to a surgical case at our center (i.e. 5.1 per cent actual share of the potential market). Carry-over effects (i.e. self-referrals after the campaign) were not measured.

Patient satisfaction outcomes

Short-term satisfaction scores, obtained from HCAHPS surveys and returned from 61 per cent of the study cohort and 63 per cent of controls, showed no differences between the DTCA and control group (Table II). Both groups were very satisfied with the surgery and the immediate outcomes. However, when patients were surveyed six months after the surgery and asked to reflect on their rCABG experiences, a significantly smaller percentage of DTCA patients reported that their expectations had been fully met (i.e. response to all three questions with ≥ 3 rating on a 1-5 scale) compared to controls (82.1 vs 95.7 per cent of patients/group, $p = 0.033$, Table II). This difference was driven by

Baseline characteristics	DTCA Responders ($n = 43$)	Control group ($n = 77$)	p-value (t-score or χ^2*)
Age (years)	62.6 ± 11.8	68.5 ± 11.8	*0.010 (2.62)*
Sex (% male)	88.4	69.7	*0.025(5.30)*
Race (% White)	90.7	88.3	0.769 (0.163)
BMI (kg/m^2)	28.9 ± 4.8	29.6 ± 5.4	0.470 (0.0725)
Diabetes mellitus (%)	37.2	47.4	0.338 (1.152)
Smoking history (%)	46.4	45.8	1.000 (0.003)
Hypertension (%)	93	93.4	1.000 (0.007)
Hyperlipidemia (%)	95.2	94.7	1.000 (0.014)
Congestive heart failure (%)	18.6	31.6	0.138 (2.351)
Peripheral artery disease (%)	7	11.8	0.533 (0.717)
Cerebrovascular disease (%)	4.7	11.8	0.324 (1.693)
Pre-existing renal failure (%)	2.3	5.3	0.652 (0.589)
Chronic lung disease (%)	4.7	19.7	*0.029 (5.104)*
Left main coronary artery disease (%)	20.9	29.9	0.390 (1.128)
Aspirin therapy (%)	95.3	97.2	0.629 (0.281)
Lipid lowering medication (%)	95.1	98.6	0.554 (1.170)
Anti-hypertensive medication (%)	88.4	94.8	0.279 (1.646)
Married (%)	84	82	0.851 (0.140)
College education (%)	53	44	0.258 (1.62)
Live within primary service area (%)	13	74	*<0.001 (75.7)*
Elective case (%)	74.4	42.1	*0.001 (11.54)*

Notes: [a]Estimated income based on zip code; *F-score for unpaired t-test or Pearson's χ^2 value for Fisher's exact test

Table I. Comparison of baseline and postoperative characteristics

	DTCA responders (n = 43)	Control group (n = 77)	p-value (t-score or χ^{2}*)
Clinical outcomes			
Bypass grafts performed (total #)	1.6 (0.66)	1.6 (0.64)	0.726 (0.603)
Operating room time (hours)	6.4 (1.5)	6.6 (2.5)	0.691 (0.500)
Time on ventilator (hours)	11.6 (8.7)	15.72 (27.8)	0.407 (−0.236)
Stay in ICU (hours)	42.5 (34.2)	75.8(155.7)	0.201 (−0.841)
Length of hospital stay (days)	5.9 (4.2)	7.9 (4.2)	*0.011 (−2.321)*
Major complication at 30 days (%)[a]	4.7	7.8	0.710 (0.438)
Duke Activity status index score[b]	21.8 (11.5)	21.2 (14.6)	0.887 (−1.232)
Satisfaction outcomes			
Short term satisfaction: (three weeks)			
HCAHPS score (1-100)[d]	86.5 (n = 26)	84.7 (n = 49)	0.299 (1.05)
"Pain was well controlled"[e]	84.2	83.5	0.443 (1.12)
Medium term satisfaction:(six months)			
Those with all expectations met (%)	82 (35 out of 43)	96 (73 out of 76)	*0.007 (0.001)*
Those with unmet expectations at 6 months (%)[f]	18.5	2.6	*0.033 (0.002)*
"time required to recover"	13.0	1.3	
"length of the incision"	7.4	2.6	
"expertise of your surgeon"	0.0	0.0	

Notes: [a]Death, stroke, renal failure, reoperation for bleeding, prolonged ventilation or sternal infection; [b]at three weeks; [c]response of either 1 or 2 to any question on the questionnaire; [d]HCAHPS surveys returned from 61% of the study cohort and 63% of controls; [e]HCAHPS Question #13; [f]expressed as per cent of total cohort; *F-score for unpaired t-test or Pearson's χ^2 value for Fisher's exact test

Table II.
Comparison of post-operative outcomes

unmet expectations (i.e. responses ≤ 2) regarding the "size of the incision" and "speed of recovery" but not the "expertise of your surgeon" (Table II).

A *post hoc* subgroup analysis comparing patients with all their expectations satisfied to patients with unmet expectations (n = 12) demonstrated that both groups did not have statistically significant differences marital status (78 vs 83 per cent married), level of education (56 vs 67 per cent college or higher) and equivalent 30 day rates of complications (6.6 vs 7.4 per cent) and satisfaction scores at three weeks (85.9 vs 85.1).

Discussion

Our study suggests that DTCA was effective at communicating to prospective patients within the lay public about a complex surgical procedure (rCABG). During the campaign, new patients arrived from outside of primary service area of the hospital to seek a second opinion from the sole program in the region that offered rCABG. This suggests that DTCA did not just cannibalize existing referrals but also actually stimulated primary demand for rCABG. Within the context of a media market already saturated with health-care advertising (Rowland, 2006), our one-year DTCA campaign generated qualified leads representing almost 8 per cent of the potential market segment (i.e. subset of patients referred for CABG that were likely suitable for rCABG). In contrast, the typical DTCA campaign from other health-care fields are expected to prompt action in < 2 per cent of their target

population (Liebman, 2001). Although many factors contributed, we speculate that the primary determinant of this response was the strong valence of rCABG as an advertising message. Prior evidence has shown that patients often have unmet information needs about less invasive surgical options (Larson *et al.*, 1996; Horwitz, 1999) and view DTCA as a helpful and legitimate source for information about complex medical topics (Bozic *et al.*, 2007; Abel *et al.*, 2009).

Other studies have found it difficult to quantify the effectiveness of hospital ads at generating patient referrals. Several unique circumstances in the New England cardiac surgical market in 2008-2009 made an estimate possible for our study. First, the ad campaign stood out to the public because of its clear purpose – to alter the speed with which a new patient-centered innovation was recognized and popularized. Among the world-class CABG programs in Boston at the time of this DTCA campaign, our center was the only that would offer rCABG to patients that expressed interest in this idea. Second, the referral channel for CABG is well established. Every patient who requires CABG has a cardiologist. Prior to DTCA, a cardiologist's referral was the sole means of a patient coming to our center for surgery. Self-referral for rCABG was a conspicuous reason to assign a patient to the DTCA cohort that could be corroborated through follow-up interviews with patients and their providers. Mandatory participation in a cardiac surgery database for all programs in the state provided details about the CABG market within the region. This enabled an accurate estimate of the number of potential candidates for rCABG during timeframe of the ads.

Control patients were provided information about rCABG by their providers and then referred to the surgeon, which is a standard practice. The DTCA group found out about rCABG from the ad and had to "self-refer", which may have created a bias in this group for patients with more self-efficacy, greater health literacy and potentially an economic motivation for faster recovery (Mackert and Love, 2011; Junewicz, 2014). A variety of studies have shown that these characteristics predict improved recovery in the setting of cardiovascular disease (King *et al.*, 2001; Jackson *et al.*, 2005). At the same time, they can set the stage for a disturbed patient–physician relationship. Many DTCA patients requested a referral for rCABG and were denied. Prior evidence suggests that such denials provoke dissatisfaction, particularly in males facing a life-threatening situation (e.g. severe coronary artery disease), (Blose and Mack, 2009). Patients that "self-refer" are often left feeling they took sole responsibility for this high-stakes decision, which creates a risk for decisional regret in the future (Nordgren *et al.*, 2007). These associations are likely generalizable to our study and, therefore, require careful consideration as our findings are interpreted.

Our study design does not allow the impact of DTCA to be teased out amid other information sources (e.g. opinions of friends, family and medical providers) and cognitive biases triggered within the minds of patients making decisions under conditions of uncertainty. It is possible that some factor other than the ads might have prompted the decisions of patients in the DTCA cohort to choose rCABG. However, our analysis suggests that the impact of such unmeasured factors was likely to have been modest. The DTCA cohort was derived from a primary service area that included a higher proportion of working age males, with more education, less chronic lung disease and a less urgent cardiac problem than controls. Prior to the DTCA campaign, Boston Medical Center had a reputation as an "inner city" surgical program that recruited patients from a much different market segment. The temporal relationship of the arrival

of a new market segment to the timing of the ad campaign strengthens our conclusion that DTCA was responsible.

One plausible explanation for the strong response to our ad campaign is that standard practice in Boston at that time did not sufficiently expose patients that needed CABG to the option of rCABG. Many of the patients enrolled in DTCA group learned about rCABG at relatively late stages in their work-ups for surgery, imposing a time constraint that could exacerbate the emotional intensity of their decision. If patients referred for CABG were routinely provided information about all available alternatives such as rCABG from their providers or by their own independent research, one would have expected less response to our mass media ads. Conversely, their response to information provided in a mass media ad implies that they would have preferred this information to be disclosed during informed consent by their providers. The providers either misunderstood or were unable to meet this expectation, creating a service gap (i.e. *Gap 1, empathy*). Prior evidence suggests that intermediaries in the surgical referral channel have been either unwilling or unable to share information about previously undisclosed and underutilized services such as less invasive surgery (Cooper *et al.*, 2014). Although the exact reasons for this channel deficiency are unclear, one possible contributor may be that many of these patients' health-care providers were unable to provide confident advice about a novel procedure for which they had no personal experience. Variation in the use of "preference sensitive" therapies such as the traditional open sternum CABG often reflects preferences of the surgeon rather than those of the patient (Wilson *et al.*, 2007). Decision aids help patients by slowing down the decision process (Rosenbaum, 2015). A Cochrane review of 86 studies on shared decision-making showed that patients provided with information through decision aids are more likely to choose surgical options that are less invasive (Stacey *et al.*, 2011). DTCA acted as a decision aid in context of this study, because it led interested patients who were often already referred for standard CABG to pursue a second opinion about rCABG, thereby closing this service gap for the desired information.

Conversely, there are also concerns about DTCA. Robotic surgery as a marketing message is known to trigger emotional responses in patients (Dixon *et al.*, 2014), and these emotions can drive patient decision-making. Ad campaigns aim to provide information vivid enough to create a patient response and generate leads (Rook, 1986), which in our case involved patient testimonials and compelling audiovisual images. Although rather mild by general advertising standards, any approach that aims to be persuasive might be seen as too "aggressive" in a health-care context. There is a risk of overriding autonomy if patients establish a favorable decision about rCABG for no other reason other than they first heard about it within the controlled framework of our ads (McKneally, 2002; Federal Trade Commission, 2009). Emotionally charged information about new medical technology can take advantage of patient vulnerability caused by their overall poor health, their search for a miraculous cure and their inability to easily verify claims (Urbach, 2016). Expensive ad campaigns can exacerbate the perception of the profit motive by the surgeon and hospital, further hindering the therapeutic relationship.

Ad claims might have "oversold" rCABG and caused unrealistic expectations from overt deception (i.e. *Gap 4, honesty*). Our study design included three safeguards against "overselling". First, we obtained prospective feedback about the ads from a multidisciplinary committee of health-care professionals at our institution. Second, we obtained retrospective feedback from the Better Business Bureau in Boston, the agency

responsible for reviewing health-care ads by non-profit hospitals. Both groups compared the ads against published evidence about rCABG (Poston *et al.*, 2008) and confirmed that the ad claims were understandable, not likely to be misinterpreted and not deceptive. Finally, we noted that the rate of unmet expectations in our DTCA cohort was similar to patients undergoing other types of high impact surgery that were not exposed to any ad claims (Sheehan *et al.*, 2007; Poston *et al.*, 2008; Schroeck *et al.*, 2008). The clinical outcomes of those with unmet expectations were not found to be different in a *post hoc* analysis.

Even if the ads did not exceed standards for deception based on regulatory and professional perspectives, it is still possible that they implicitly instilled unrealistic expectations among the DTCA cohort. To evaluate this possibility, we obtained feedback from all study patients six months after rCABG. This demonstrated a rate of negative disconfirmation that was significantly higher in the DCTA cohort than controls (18 vs 2.6 per cent, $p = 0.007$). Most patients find it difficult to rate their experience about a highly technical service such as rCABG (Dixon *et al.*, 2014). Psychological theory suggests that patient's perceptions and memory recall for a complex service are often influenced by the positive framing effect of DTCA, which serves as a favorable cue that can substitute for independent judgment (Hoch and Ha, 1986; Braun-LaTour and LaTour, 2005). The DTCA cohort was exposed to ads prior to surgery, but our campaign had such a high degree of penetration that both groups were likely to be exposed at some point between surgery and their six-month survey. This caused a systematic difference in the timing of ad exposure relative to the performance of rCABG that may help explain why unmet expectations at six months varied between groups. Controls exposed to ads after surgery may have responded to the positive framing effects of the ad, whereas only the DTCA cohort was exposed prior to surgery, which may have had the main effect of setting high expectations. The DTCA group had more education than controls. Prior research suggests that education, as an indicator of cognitive ability, moderates the effects of framed advertising (Sicilia *et al.*, 2005). Therefore, the DTCA group may have been more capable than controls at discriminating the ad claims from their perceptions and considered this ability as being more diagnostic than an ad. Consistent with this idea and the findings of others, the DTCA group had gaps in their expectation vs perceived quality (i.e. *Gap 5*) around two central and relatively unambiguous messages of the DTCA campaign that were relatively easy to judge ("size of the incision", "speed of recovery") but not about more technical issues that are difficult to judge (e.g. "expertise of the surgeon"). Our protocol did not control for exposure to the mass media ads after surgery and did not directly assess its psychologic influence, so these ideas remain highly speculative.

Taken together, our analysis suggests that DTCA improved a gap related to a patient's expectation for information that is important to them (i.e. *Gap 1, empathy*), but a potential tradeoff was the risk of a new gap (i.e. *Gap 5, functional quality*). Even if the ads themselves did not directly cause any service gap, a mere association alone is important. Dissatisfaction with any aspect of health care directly relates to poor clinical outcomes and future risk of a malpractice claim. This underscores the need for providers of patients exposed to DTCA to spend time during the initial consult, pre- and post-operative hospital stay checking and managing and correcting expectations so that they are aligned with correct interpretations of ad claims. In response to this study, we implemented changes to improve communication (e.g. 24-h access to the surgeon's cell phone and a secure e-mail after each initial office visit).

Although corrective action such as this is an extra burden for health-care providers (Gilbody *et al.*, 2005; Bozic *et al.*, 2007), it is an essential one to minimize "false-hopes" that can be created (albeit completely indirectly) on aspects not even addressed by the ad. Our experience illustrates that careful forethought is required to identify and manage potential gaps in service quality that may result from DTCA promotion of a high-risk procedure such as rCABG.

An alternative point of emphasis for future ads might be to highlight the intrinsic value of a second opinion. Growing evidence suggests that being provided choices, particularly those that depend on the context of a patient's social circumstances and willingness to accept risks, improves satisfaction and outcomes (King *et al.*, 2009). In reality, any surgical patient (whether robotics or DTCA is involved) is at risk for an outcome that is less than optimal. The fact that results are never guaranteed is often not reflected in the current messages provided in DTCA about robotic surgery (Dixon *et al.*, 2014). External marketing that focuses on the value of a second opinion is more likely to remain consistent with the information provided as part of informed consent about rCABG that is more dispassionate and reflects the reality of risk.

Limitations

An important limitation of our study was the lack of validated instruments to survey rCABG patients. We screened for the DTCA cohort by calling patient's referring providers. Alternatively, a dedicated toll-free number or a website address assigned to this specific promotion could have been used. This more accurate method for confirming group assignment might have excluded some patients from the DTCA cohort, which would affect our conclusions about ad penetration but not the influence of ad exposure on unmet expectations. There are no available tools for assessing disconfirmation of CABG patients, so we adopted the standard SERVQUAL survey to our purposes. Although not formally validated as a measure of negative disconfirmation, our survey was context- and objective-specific. Measurement items were directed explicitly at those claims made by the ad that could cause negative disconfirmation, thereby avoiding the ceiling effect associated with generic satisfaction surveys after heart surgery. We chose the six-month time-point to minimize the chance for a recall bias and because this is generally accepted to represent a final outcome for the aspects of care that were investigated. Our overall approach was adopted from prior studies of post-surgical disconfirmation (Schroeck *et al.*, 2012) and has been shown to improve response rates without affecting the reliability and validity of this instrument. Our assessment of unmet expectations required subjects to remember six months after surgery what their expectations were prior to surgery. This type of memory is subject to inaccuracies and bias. Future research should assess DTCA respondent expectations before surgery to provide a more objective comparison with their perceptions measured after the surgery. Finally, we were aware that carry-over effects (i.e. patients who sought rCABG after the completion of the campaign) may have existed, but measuring them was not within the scope of this study. The fact that this type of confounding is possible weakens any conclusion that the ads had a causal effect on expectations.

Conclusion

A mass media ad can only be expected to alter a serious and potentially life-threatening health-care decision when it provides a compelling message. The penetration of our

DTCA campaign estimated in our study suggested that rCABG was a topic that provided this type of compelling message. Caution should be taken in extracting strong implications from these results given the nature and limitations of the study. Nevertheless, the main finding of a difference in satisfaction at six months post-surgery between those responding because of the DTCA campaign and those referred the traditional way warrants further research. More unintended service gaps occurred in our DTCA cohort despite our efforts to manage expectations and build trust. As marketing efforts continue to expand at US hospitals, our findings suggest the need for further research into DTCA used to promote high-risk surgical procedures. Such research could be used to help refine the messages of the ads and discover better ways to manage expectations to improve the overall effectiveness of these campaigns.

Notes

1. www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion502.page?
2. www.sts.org/about-sts/policies/advertising-and-publicity-policy
3. www.youtube.com/watch?v=nSH_gpb89ho
4. www.youtube.com/watch?v=gS-5BQylTT8
5. Federal Register/Vol. 78 No. 160; § 412.140 (f.1-2).
6. www.hcaphsonline.org
7. massdac.org/sites/default/files/reports/CABG%20FY2008.pdf
8. www.hcahpsonline.org/files/HCAHPS%20V9.0%20Appendix%20A%20-%20Mail%20Survey%20Materials%20(English)%20March%202014.pdf

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