TBM

BRIEF REPORT

Association of patient navigation with care coordination in a Lynch syndrome screening program

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Abstract

Lynch syndrome (LS) identification leads to improved health outcomes. Universal tumor screening (UTS) facilitates LS identification among colorectal cancer (CRC) and uterine cancer (UC) cases; institutional management affects screening program implementation and outcomes. There has been limited study of institutional UTS program care coordination needs, including patient navigation of genetic counseling referrals. We examined the influence of patient navigators on access to cancer genetic services among LS UTS screen-positive cases within a single institution. Electronic health record review of screen-positive CRC and UC cases for a 12-month period assessed the relationship between patient navigation and follow-through to genetic services. Among 451 newly diagnosed CRC (n = 175) and UC (n = 276) cases, 96 (21%; 28 CRC/68 UC cases) had abnormal UTS results. Among these, 66 (69%) showed *MLH1* promoter hypermethylation (i.e., screen-negative). Of 30 screen-positive cases, 16 (53%) received navigation services. Among these, 14/16 (88%) and 13/14 (81%) underwent genetic counseling and testing, respectively; 7/13 (54%) had pathogenic or likely pathogenic variants detected. Among non-navigated screen-positive patients, 2/14 (14%) were excluded due to incomplete UTS results. Five of the remaining 12 cases (42%) sought genetic counseling, 4/12 (33%) underwent genetic testing; 1/4 (25%) tested positive for a pathogenic variant. The difference in navigated (88%) versus non-navigated cases (42%) undergoing genetic counseling was statistically significant (p = .02). Patient navigation was associated with follow-through to genetic counseling and testing services among LS screen-positive cases. This model deserves additional prospective investigation to confirm these findings and to assess their generalizability.

Keywords

Lynch syndrome, Universal tumor screening, Genetic counseling, Patient navigators, Care coordination

Implications

Practice: There may be an association between patient navigator–directed care coordination and appropriate follow-through genetic counseling for colorectal cancer and uterine cancer cases with positive Lynch syndrome (LS) universal tumor screening (UTS) results.

Policy: The full impact of LS UTS can only be realized if those who screen positive have access to genetic counseling and testing services.

Research: Future research is needed to explore both patient navigation and other care models aimed at limiting gaps in institutional LS screening protocols.

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Cite this as: *TBM* 2018;8:450–455
doi: 10.1093/tbm/ibx078

Published by Oxford University Press on behalf of the Society of Behavioral Medicine 2018.

INTRODUCTION

Lynch syndrome (LS) is the most common hereditary cause of colorectal cancer (CRC) and uterine cancer (UC), accounting for about 2%–5% of all CRC and UC cases nationally [1]. Individuals with LS have a 25%–70% lifetime risk of CRC and among women, a 30%–70% chance of uterine cancer, with increased risks for several other malignancies. There are effective cancer risk reduction and prevention strategies available to those with LS and their affected family members [2], highlighting the importance of identification of at-risk individuals and effective care coordination for both probands and at-risk relatives.

Recognition of the importance of LS identification is manifested in the Healthy People 2020 developmental objective: "Increase the proportion of persons with newly diagnosed colorectal cancer who receive genetic testing to identify Lynch syndrome (or familial colorectal cancer syndromes)." [3] Reliance on established LS clinical criteria (i.e., Bethesda guidelines) or early age at cancer diagnosis fails to identify 25%–70% of those with this condition [4–8]. These data show that systematic approaches are needed to identify LS risk.

LS is associated with germline mutations in DNA mismatch repair (MMR) genes *MLH1, MSH2, MSH6*, and *PMS2*. Additionally, genomic *EPCAM* rearrangements can result in silencing of the downstream *MSH2* gene. Universal tumor screening (UTS) of CRC and UC specimens for loss of MMR enzyme immunohistochemical (IHC) expression and/or microsatellite instability (MSI) has been shown to improve LS identification compared with reliance on clinical risk assessment guidelines [9].

LS UTS was recommended by the Evaluation of Genomic Applications in Practice and Prevention working group, funded by the U.S. Centers for

Disease Control and Prevention Office of Public Health Genomics, based on evidence of analytic and clinical validity, as well as clinical utility [9, 10]. Economic models show that CRC UTS value is comparable with other well-established U.S. preventive health care services [11]. U.S. and European recommendations include UTS of CRC and UC cases using MMR enzyme IHC, with or without MSI testing, as a way to identify potential LS risk [2, 12]. These recommendations have been incorporated into National (U.S.) Comprehensive Cancer Network (NCCN) guidelines [13].

UTS protocols vary interinstitutionally [14, 15] and may also vary within a given institution. Laboratory protocols often include tumor-based IHC testing with or without MSI testing to identify MMR deficiency. Among MLH1-deficient tumors, reflex *BRAF* mutation testing and/or *MLH1* promoter hypermethylation testing of CRC cases and hypermethylation testing of UC cases can be performed as a means to triage patients such that those with evidence of somatic *MLH1* promoter hypermethylation are not referred for genetic counseling.

The full benefit of UTS can only be realized if those with suggestive UTS results (screen-positive) access genetic counseling services and undergo appropriate germline genetic testing to (i) confirm an LS diagnosis, (ii) provide appropriate risk reduction management recommendations to LS-affected probands, and (iii) initiate cascade testing of families (effectively and efficiently triaging at-risk relatives for genetic counseling, genetic testing, and risk reduction services).

Involvement of genetic counselors has been shown to improve care coordination among institutions performing UTS, as measured by patient follow-through with genetic counseling and testing services [16]. However, in the community setting, focused UTS care coordination by genetic counselors is often not feasible due to high counselor clinical demands and limited geographic access. Patient navigation has developed as a medical intervention model directed at identifying and overcoming barriers to cancer care [17] with demonstrated evidence of the benefit of navigation services on adherence to cancer screening and compliance with follow-through care after a screen-positive result [18]. There has been little study of the influence of patient navigators on provision of cancer genetic counseling and testing services among LS screen-positive patients [19]. The goal of this observational natural history study was to examine the potential association between patient navigators and institutional follow-through to cancer genetic counseling and testing services among UTS screen-positive patients.

METHODS

Setting and patient population

This study was implemented at Maine Medical Center Cancer Institute's Cancer Risk and Prevention Clinic in Scarborough, Maine. Maine Medical Center (MMC) is the state's largest health care facility, playing a role as both a community hospital and a tertiary center, serving the state and portions of Northern New England. At the time of study in 2015–2016, the Cancer Risk and Prevention Clinic was one of the two institution-based, genetic counselor-supported cancer genetic programs in Maine.

This work was considered exempt from review by the MMC IRB because it was a quality improvement study and data analyzed did not include patient identifiers. All patients undergoing surgery under the care of MMC-associated surgeons from May 1, 2015 to April 30, 2016 due to a diagnosis of CRC and/or UC were included. Total numbers of CRC and UC patients undergoing surgery in the 12 month period were provided by MMC's Oncology Information Services office.

Maine Medical Center UTS protocol

The MMC pathology UTS protocol included universal IHC staining for all four LS MMR enzymes including MLH1, MSH2, MSH6, and PMS2 with MSI testing ordered, at the discretion of the pathologist. Reflexive *MLH1* promoter hypermethylation testing with or without *BRAF* V600E mutation testing was done for all CRC MLH1 deficient CRC cases, whereas UC cases lacking MLH1 expression were subjected only to *MLH1* promoter hypermethylation testing.

UTS screen-positive cases were defined as individuals with abnormal IHC and/or MSI results, discordant UTS results (i.e., absence of all MMR enzymes) and, in the case of MLH1-deficient cases, no evidence of *MLH1* promoter hypermethylation (unless associated with a personal history of multiple primary LS-associated cancers). Screen-negative cases included individuals with normal testing or those with evidence of tumor *MLH1* promoter hypermethylation in the absence of a personal history of multiple primary LS-associated cancers. All abnormal UTS results (including those with evidence of *MLH1* promoter hypermethylation) were reported as an addendum in the pathology report that was available through MMC's electronic health record (i.e.,EPIC), accessible to MMC-based treating surgeons and other institutional multidisciplinary team members involved in the care of the patient, including patient navigators.

Patient navigation and tracking

During the study period (2015–2016), MMC staffed two patient navigators (both Oncology Nursing Society–certified registered nurses) focused on cancer treatment-related care coordination for CRC and UC patients, respectively. Screen-positive UTS results were typically communicated by phone or email from the pathologist to the treating surgeon, the patient navigator or both. Independent

of pathology UTS reporting, navigator referrals were at the discretion of one or more members of MMC-based multidisciplinary care teams. Patient navigators kept lists of the screen-positive patients as reported by pathologists, and helped to coordinate referrals for genetic counseling and consideration of testing.

The MMC Department of Pathology kept a master list ("pathology master list") of CRC and UC patients with abnormal LS UTS results. The pathology master list of those with abnormal results was provided to Cancer Risk and Prevention Clinic staff for subsequent chart review. In addition to the pathology master list of abnormal UTS results, the two patient navigators provided Cancer Risk and Prevention Clinic staff with their lists of patients having abnormal UTS results ("navigators' list").

Chart review

A clinical Cancer Risk and Prevention Clinic team member (S.M.) performed an unblinded electronic health record (EHR)-based chart review of all patients included on the pathology master list using a coding form. Data collected for each screen-positive individual included clinical cancer history (i.e., history of multiple primary LS-associated cancers), age at cancer diagnosis, LS UTS results (including *MLH1* promoter hypermethylation test results, when performed), referral for cancer genetic counseling, provision of genetic counseling, if genetic testing was done and test results. The two lists (pathology master list and navigators' list) were cross-referenced for differences and patients were separated into two groups: (i) navigated patients and (ii) non-navigated patients. Only screen-positive individuals appearing on the pathology master list were included in the association analysis.

Data analysis

Simple counts and percentages were used to describe our data. Group comparisons were restricted to clinical characteristics as well as analysis of the difference in follow-through to genetic counseling among navigated versus non-navigated cases using Fisher's exact test evaluated at an α error rate of .05.

RESULTS

UTS screening

During the study period, there were a total of 451 patients with newly diagnosed CRC (n = 175) and UC (n = 276; Fig. 1). Although this could not be directly confirmed in this study, it was expected that nearly 100% of CRC and UC specimens were screened for LS. Among these, 101/451 (22%) cases had initial abnormal IHC and/or MSI results. This included 33 CRC and 68 UC cases. A total of five CRC cases were excluded from further analysis because their surgeons were not MMC-based. This left a total of 96 (21%) cases with initial abnormal UTS results (28 CRC and 68 UC cases).

Among the 96 patients with abnormal IHC and/or MSI results, 66/96 (69%) were the result of *MLH1* promoter hypermethylation, including 14 CRC and 52 UC cases (Fig. 1). Two of ninety-six (0.02%) had incomplete UTS results documented in the MMC EHR. Two cases with evidence of *MLH1* promoter hypermethylation were included in the screen-positive group due to histories of multiple primary LS-associated cancers (one with multiple primary CRCs and the second with both UC and ovarian cancer). A total of 30 patients (14 CRC and 16 UC, including six cases with multiple primary cancers) were classified as screen-positive (including two cases with incomplete UTS results).

Navigation status

A total of 19 patients (10 CRC, 9 UC, including two cases with multiple primary cancers) reported on the pathology master list were included on the navigators' list. Three of these cases (all CRC) had evidence of *MLH1* promoter hypermethylation and

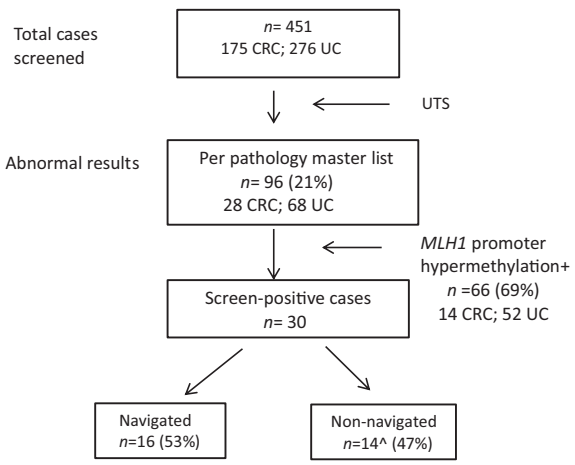

Fig 1 | UTS results. *CRC* colorectal cancer; *UC* uterine cancer; *UTS* universal tumor screening. ^Includes two cases with incomplete UTS results recorded that were excluded from further analysis.

therefore were excluded from further analysis, leaving a total of 16 screen-positive navigated cases.

A total of 14 cases (six CRC and eight UC, including four cases with multiple primary cancers) were not reported on the navigators' list. Two of these were excluded from further analysis due to incomplete UTS results (12 total non-navigated screen-positive individuals).

Gender, age, disease characteristics, and incomplete UTS result documentation of screen-positive patients in the navigated versus non-navigated groups are summarized in Table 1.

Navigated patients

Shown in Table 2, all 16 screen-positive navigated patients included on the pathology master list were offered referral for genetic counseling. Among these, 14/16 (88%) were seen by a genetic counselor (n = 13) or received follow-through genetic care from an oncologist (n = 1), 1/16 declined genetic counseling (6%), and 1/16 (6%) was lost to follow-up because postsurgical care was received at another institution. One counseled patient (CRC) with discordant UTS results (MLH1 deficient; BRAF− and hypermethylation+) was determined by the genetic counselor to be at low risk and genetic testing was not indicated. The remaining 13 screen-positive patients underwent genetic testing with 7/13 (54%) testing positive for a pathogenic or likely pathogenic variant, 5/13 (39%) had no detectable variant, and 1/13 (8%) was determined to have a variant of uncertain significance.

Non-navigated patients

There were a total of 14 screen-positive individuals (six CRC and eight UC, including four with multiple primary cancers) on the pathology master list who were not included on the navigators' list (non-navigated patients, Table 2). In 2/14 (14%) of these cases, UTS results were incomplete (i.e., not reported in EHR [n = 1] or no evidence of hypermethylation testing in an MLH1-deficient UC case [n = 1]). Among the remaining 12 screen-positive non-navigated cases, 5/12 (42%) were evaluated by a genetic counselor and four of these underwent genetic testing, 1/4 (25%) tested patients proved to have an LS-associated pathogenic variant and no variants were detected in the remaining three.

Comparisons

There was a statistically significant difference in the percentage of navigated cases (14/16; 88%) versus non-navigated cases (5/12; 42%) with EHR-based record of follow-through to genetic counseling (p = .02).

DISCUSSION

To the best of our knowledge, there have been no published studies exploring the influence of patient navigation on follow-through to genetic counseling and testing services among those with abnormal LS UTS results. This observational study provides preliminary evidence that patient navigation may be associated with higher rates of access to genetic services by UTS screen-positive individuals with CRC and UC. The results described here may also suggest a patient navigator role in supporting LS UTS procedures at an institutional level. Specifically, among non-navigated patients, there were two individuals with incomplete screen results documented in the EHR, whereas none of the navigated patients had incomplete results recorded. Importantly, we could not determine from the record the reason for incomplete reporting of/or access to UTS results or the potential role of clinical factors in this regard. Relative to programmatic efficiency, a total of 3/19 (16%) patients included on the CRC patient navigator's list had evidence of *MLH1* promoter hypermethylation. Although it was not possible to tell from the EHR why these patients were reported to the navigator, this is an important issue relative to patient navigator effort and efficiency.

CRC and UC management typically involves complex interdisciplinary care, necessitating effective and efficient care coordination. Providers often include a number of cancer specialists (i.e., surgery or gynecologic oncology, medical oncology, and radiation oncology) in partnership with both primary

Table 1 | Screen-positive cases: clinical characteristics

Measure	Navigated patients (n = 16)	Non-navigated patients (n = 14)	p-Value*
Gender, n (%)			
Female	13 (81)	12 (86)	NS
Age in years, range (mean)	38–88 (62)	41–77 (59)	
Cancer type, n (%)			
CRC	7 (44)	7 (50)	NS
UC	9 (56)	7 (50)	
Multiple primary cancers, n (%)	2 (13)	4 (29)	NS
Incomplete UTS result documentation, n (%)	0 (0)	2 (14)	NS

CRC colorectal cancer; *UC* uterine cancer; *UTS* universal tumor screening; *NS* not significant.

*Fisher's exact test. No comparison was run for the "Age in years, range" measure.

Table 2 | Follow-through care: screen-positive navigated ($n = 16$) versus non-navigated patients ($n = 14$[a])

Measures	Navigated *n* (%)	Non-navigated *n* (%)	*p*-Value[b]
Follow-through			
Care transferred	1 (6)	NA	
Declined genetic counseling	1 (6)	NA	
Underwent genetic counseling	14* (88)	5 (42)	.02
Genetic testing pursued	13 (81)	4 (33)	
Genetic test result			
Positive or likely positive	7 (54)	1 (25)	
Negative	5 (39)	3 (75)	
VUS	1 (8)	0 (0)	

GC genetic counselor; *VUS* variant of uncertain significance; *NA* data not available.

[a]Two non-navigated had incomplete UTS results recorded in the EHR so were excluded from further analysis.

[b]Fisher's exact test. Comparison was run *only* for the "Underwent genetic counseling" measure.

*One navigated patient received follow-through genetic care via their oncologist.

care providers and a range of other health professionals (pathologists, genetic counselors, nurses, social workers, palliative care specialists, and others). The complexity of care and need for interdisciplinary management highlights the need for proven systematic institutional approaches to care coordination among those with abnormal UTS results and/or clinical or family risk factors for LS, with the ultimate goal of effective and efficient triage to cancer genetic counseling and testing services. Variations and gaps in institutional UTS follow-up processes and procedures can reduce the percentage of LS screen-positive patients appropriately or successfully referred for genetic counseling and consideration of genetic testing. Streamlining UTS procedures, limiting gaps in and barriers to patient contact, as well as effective and efficient interdisciplinary care coordination are patient navigator roles that may optimize UTS effectiveness and outcome [16].

This study has a number of weaknesses. First, it was observational in nature, and the investigators, staff, and participants were aware of the services received. Second, it involved a small number of patients from a single institution, so any association reported here is merely suggestive. The results should be viewed as hypothesis generating relative to the potential influence of patient navigators on institutional LS UTS care coordination. Third, there were significant limitations relative to study design (i.e., EHR review) as well as the inability to assess the influence of institutional systems on outcomes. These include incomplete EHR reporting and/or review, lack of access to charts from outside institutions, inability to assess medical or sociodemographic barriers to genetic counseling and testing, and study team knowledge gaps regarding workflows relevant to patient care coordination that were not evident in the EHR. Fourth, it was not possible to determine if every CRC and UC case was subjected to UTS. This is a critical feature to any successful UTS program and the study of care coordination in this regard. Fifth, it was not clear why some screen-positive individuals on the pathology master list were included on the navigators' list while others were not. There may have been confounding systematic, medical, and sociodemographic differences between these populations, unrelated to navigation status. Sixth, this experience is that of a single institution in a limited geographic region, and differences in characteristics of both the clinicians involved and the patients studied could greatly affect outcomes.

Prospective randomized studies are necessary to validate our observations. Additional work should explore both patient navigation and other models of care aimed at limiting gaps in institutional LS UTS protocols, to include the potential influence of medical and sociodemographic factors on care coordination and access to both genetic services and ongoing high risk care among those with LS. Finally, research focused on improving inter- and intra-disciplinary communication at both the institutional and health system levels is needed to more fully understand barriers to genetic counseling or testing among those at risk for LS and the role of patient navigators in overcoming these barriers. Ongoing research in this area promises to advance national precision medicine efforts with a focus on improving outcomes among individuals with or at risk for LS [17].

Acknowledgments: We thank Jessica Cary, MS, RN, CGC for her support of data collection and Norma Albrecht for her assistance in manuscript preparation. This work was performed within the institution for quality control assessment. It was not funded by any external sources.

Compliance with Ethical Standards

Conflict of Interest: None declared.

Authors' Contributions: Conception or design of the work (Susan Miesfeldt, W. Gregory Feero, Frances L. Lucas, Karen Rasmussen); Data collection (Susan Miesfeldt, Karen Rasmussen); Data analysis and interpretation (Susan Miesfeldt, Frances L. Lucas, Karen Rasmussen); Drafting the article (Susan Miesfeldt, W. Gregory Feero, Frances L. Lucas, Karen Rasmussen); Critical revision of the article (Susan Miesfeldt, W. Gregory Feero, Frances L. Lucas, Karen Rasmussen); Final approval of the version to be published (Susan Miesfeldt, W. Gregory Feero, Frances L. Lucas, Karen Rasmussen).

Primary Data: The manuscript has not been submitted elsewhere. The findings reported here have not been published. There has been no previous reporting of the data. The authors have full control of the primary data and agree to allow the journal to review their data, if required.

Ethical Approval: The MMC commits to apply the *Ethical Principals and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, generally known as the "Belmont Report." This manuscript does not contain any studies with animals performed by any of the authors.

Informed Consent: This work was considered exempt from IRB review because it was a quality improvement study and data analyzed did not include patient identifiers.

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