The Pure-Vu® Colon Cleansing System Reduces Lifetime Costs and Incidence of Colorectal Cancer (CRC) – A Cost Minimization Analysis

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BACKGROUND:

Bowel prep is a major barrier to patient compliance with colonoscopy. Up to 38% of patients do not complete their bowel prep due to poor palatability and/or intolerance of prep volume. Therefore, up to 25% of patients arrive for their colonoscopy with an inadequate prep. This prolongs procedure time, decreases cecal intubation rate, reduces adenoma and neoplasm detection, increases adverse events and requires repeated colonoscopy exams all leading to increased costs. The Pure-Vu® System connects to standard commercially available colonoscopes to facilitate intra-procedural cleaning of poorly prepped colons by simultaneously irrigating and suctioning to evacuate feces and fluids.[1,2,3]

The Pure-Vu System: Fits over most standard colonoscopes, allowing physicians to cleanse the colon in a safe and effective manner to gain clear visualization of the colon mucosa.

AIM:

We performed a cost-minimization analysis simulating the average lifetime costs and incidence of new CRCs comparing colonoscopy using the Pure-Vu System (PVC) vs. standard colonoscopy (SC).

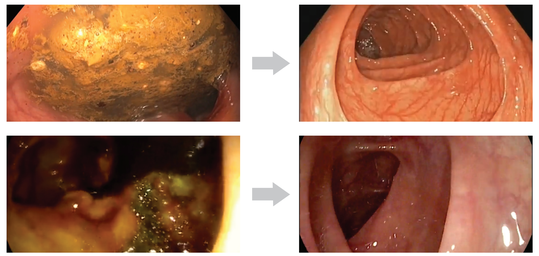
METHODS:

A Markov model was developed comparing the use of PVC in up to 25% of all colonoscopy procedures vs. SC. The model analyzed patients at both average and high-risk for CRC. Patients were cycled through the model based on the probability of finding an adenoma. Probability of follow up colonoscopy was based on colonoscopy findings and the probability of developing CRC based on follow up care. We assumed an inadequate bowel prep rate of up to 25% for the SC cohort and 5% when using PVC. Cost inputs were based on 2017 Medicare reimbursement. Cost of Pure-Vu was set at $350. Sensitivity analyses over a wide range were performed to identify key drivers of costs and new CRCs.

Table 1: Input Variables Used in the Cost-Minimization Model

Variable	Value (Sensitivity range evaluated)
Compliance screening CRC[4]	Mean 60%; range (0-100%)
Probability of inadequate prep SOC[5]	25% (range 5-30%)
Probability of complications colonoscopy[6]	0.4% (range: 0-1%)
Compliance with surveillance post initial negative screen[7]	Mean 58%; range (40-90%)
Compliance with surveillance post adenoma identification[7]	90-95%
Probability of adenoma[8]	30% (0-50%)
Probability adenoma cancerous[9]	0.4% (0-1%)
Probability early vs. late stage cancer[10]	85%/15%
CRC – probability over life of patient – average risk[4]	4.6%
CRC – probability over life of patient – high risk[11]	6-6.2%
Life expectancy after diagnosis of early stage CRC[12]	24 years
Life expectancy after diagnosis of late stage CRC[12]	3.8 years
Cost colonoscopy no polyp[13]	$1,020
Cost colonoscopy polyp[13]	$1,315
Cost treatment early stage cancer – year 1[14]	$52,640
Cost treatment early stage cancer - ongoing[14]	$4,425
Cost treatment early stage cancer – last year of life[14]	$16,840
Cost treatment late stage cancer – year 1[15]	$80,640
Cost treatment late stage cancer - ongoing[15]	$5,960
Cost treatment late stage cancer – last year of life[15]	$166,670
Cost complications[6]	$10,425

Before and After The Pure-Vu™ System Use



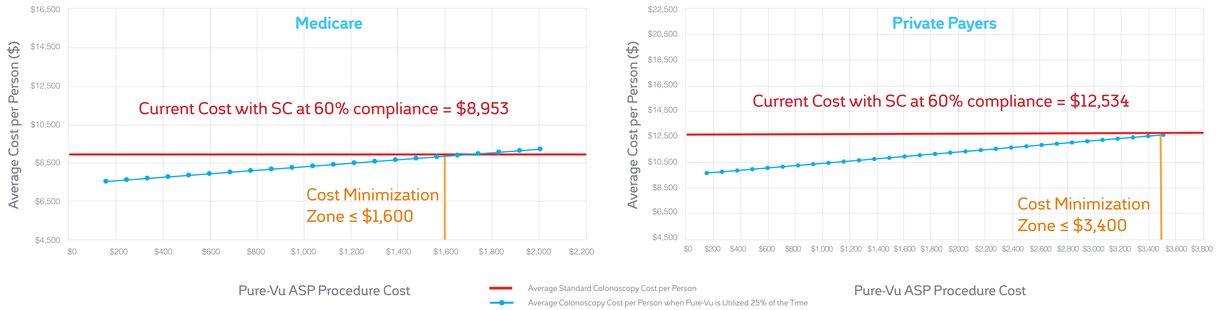
RESULTS:

See Table 2 for overall model outcomes. Using a 60% adherence rate of CRC screening with colonoscopy, the amount of developed cancers in high risk population was reduced from 0.53 to 0.34 comparing the use of SC and PVC, respectively. Under the same adherence rate, PVC was found to be cost saving as compared with SC in both average and high-risk patients (Avg risk patient costs: PVC: $4,961, SC: $5,866; High risk patient costs: PVC: $7,820, SC: $8,953). Analysis related to repeated colonoscopy procedures due to inadequate prep found that after accounting for a $350 cost for the device, PVC decreases cost in these procedures by 77-82% with a cost-savings of $323/$458 and $804/$951 for average and high risk Medicare/Private Payer patients respectively.

Table 2: Assumes 2017 Screening Recommendations of the U.S. Multi-Society Task Force of Colorectal Cancer (MSTF) and 2012 AGA Recommendations for Surveillance

	Inadeq. Prep rate	Compliance to colonoscopy	Early CRC – average risk	Late CRC – average risk	Early CRC – high risk	Late CRC – high risk
Including Pure-Vu procedure	5%	60%	2.16%	0.4%	2.9%	0.51%
SOC	25%		3.1%	0.6%	4.6%	0.8%

Graph 1: Average Standard Colonoscopy Cost vs. Average Colonoscopy Cost When Pure-Vu is Utilized (Over Lifetime in High Risk Patients)



CONCLUSIONS:

Improving the inadequate bowel prep rate via Pure-Vu leads to lower costs and a lower projected incidence of CRC in average and high-risk patients over a lifetime time horizon. This is primarily due to earlier identification of adenomas through improved visualization provided by Pure-Vu and polypectomy. Cost savings from Pure-Vu are driven by the reduced need for follow up colonoscopy procedures due to inadequate preps.

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