



# Sublingual Hyoscyamine versus Glucagon on the Diagnostic Performance of Multi-Parametric MRI in Detecting Prostate Cancer

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## Background:

- The prostate gland sits anterior to the rectum, and inferior to the remainder of the gastrointestinal tract (Figure 1).
- IV/IM antispasmodics are typically administered during multi-parametric MRI (mpMRI) to reduce motion blur subsequently improving image quality (IQ).
- Glucagon, a naturally occurring hormone, has traditionally been utilized during mpMRI in the United States (U.S.), however recent studies have questioned its net benefit<sup>1</sup>.
- Glucagon has a rapid onset of action, with the effective duration lasting approximately 20-30 minutes, shorter than the average mpMRI<sup>2</sup>.
- Outside the U.S., hyoscine N-butyl bromide (Buscopan), an anticholinergic/antimuscarinic has shown promising improvements in mpMRI IQ, however, lacks FDA approval<sup>3-6</sup>.
- Hyoscyamine, another drug that acts as an anticholinergic/antimuscarinic, is available in a sublingual (SL) form (Levsin) and acts similarly to Buscopan.
- SL hyoscyamine has an onset of approximately 2-3 minutes, with an effective duration of 4-6 hours<sup>7</sup>.
- Available literature lacks research on the benefit of SL hyoscyamine as an anti-spasmodic in mpMRI.

## Objective:

- To evaluate the effectiveness of SL hyoscyamine on improving IQ and diagnostic accuracy of mpMRI in patients with prostate cancer (Pca) when compared to glucagon.

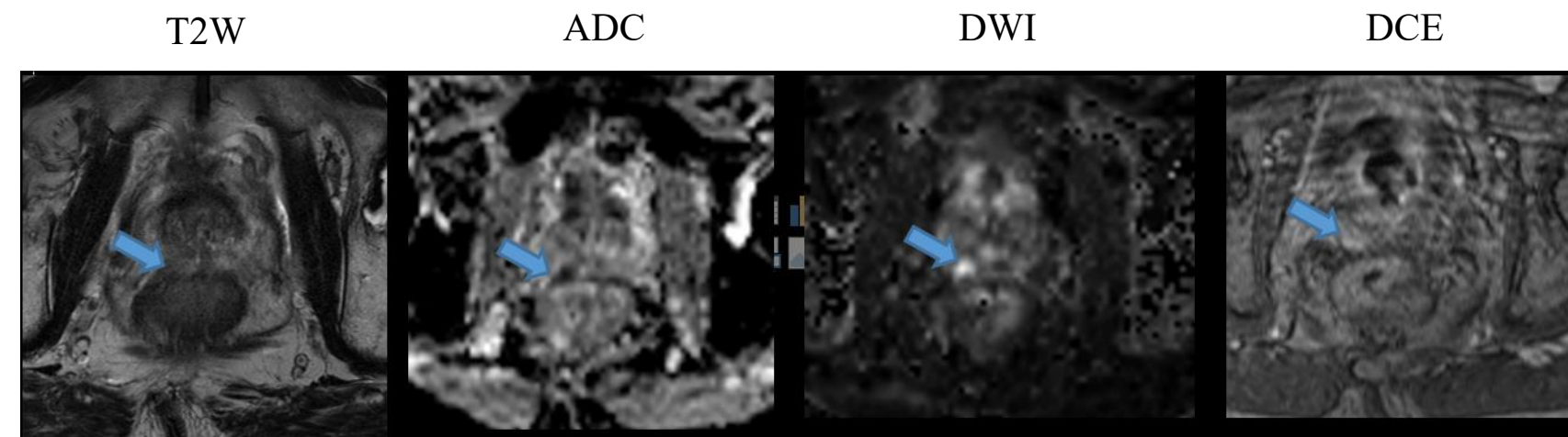


Figure 1: mpMRI sequences displaying a suspicious lesion in the right peripheral zone of prostate (Blue arrow). Motion artifact from rectal peristalsis compromising the image quality on T2W and DWI/ADC images.

## Methods:

- Electronic medical records of patients with biopsy proven PCa will be retrospectively assessed for mention of administration of glucagon, or SL hyoscyamine.
- Imaging from both administration groups will be assessed by two radiologists utilizing standardized rubrics, blinded to individual administration.
- The major outcomes of the study will focus on IQ, and diagnostic accuracy.
- IQ will be assessed through two standardized rubrics:
  - Prostate Image Quality Assessment (PI-QUAL) (Table 1)<sup>8</sup>.
  - “In-house” Assessment based on a 5-point Likert scale scoring motion blur, and anatomical delineation of:
    - Prostatic capsule
    - Seminal vesicles
    - Ejaculatory ducts
    - Neurovascular bundle
    - Sphincter muscle
- Diagnostic accuracy will be assessed based upon Prostate Imaging Reporting and Data System (PI-RADS) scoring for mpMRI image accuracy, and Gleason scoring for pathological confirmation<sup>9</sup>.
  - PI-RADS  $\geq 3$ , and a Gleason score  $\geq 7$  will be considered a positive result for prostate cancer.

## Results:

- The study is still under development, however SL hyoscyamine (Levsin) is anticipated to outperform glucagon by increasing both image quality, and diagnostic accuracy.
- When compared to previously established data on diagnostic accuracy, both glucagon and SL hyoscyamine are expected to increase diagnostic accuracy, when compared to no antispasmodic.

## Conclusions:

- Although glucagon has traditionally been used as the drug of choice for mpMRI, our team predicts that due to SL hyoscyamine’s extended duration of action, SL hyoscyamine will yield better IQ, ultimately leading to improved diagnostic accuracy.
- Additionally, SL hyoscyamine will improve patient experience through decreased needle encounters, while also improving cost-effectiveness of examination.

## References:

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PI-QUAL score	Criteria	Clinical implications
1	All mpMRI sequences are below the minimum standard for diagnostic quality	It is NOT possible to rule in all significant lesions *
2	Only one mpMRI sequence is of acceptable diagnostic quality	It is NOT possible to rule out all significant lesions *
3	At least two mpMRI sequences taken together are of acceptable diagnostic quality	It is possible to rule in all significant lesions It is NOT possible to rule out all significant lesions
4	Two or more mpMRI sequences are independently of optimal diagnostic quality	It is possible to rule in all significant lesions
5	All mpMRI sequences are of optimal diagnostic quality	It is possible to rule out all significant lesions

PI-QUAL = Prostate Imaging Quality; mpMRI = multiparametric magnetic resonance imaging.  
\* Therefore reports should not include Prostate Imaging-Reporting and Data System (PI-RADS) or Likert scores.

Table 1: Prostate Imaging Quality (PI-QUAL) Assessment Scoring Guide