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LAMPIRAN 1 REKOMENDASI ETIK PENELITIAN

KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN
RSPTN UNIVERSITAS HASANUDDIN
RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.
Contact Person: dr. Agussalim Bukhari.,MMed.PhD. SpGK. TELP. 081241850858, 0411 5780103, Fax : 0411-581431

REKOMENDASI PERSETUJUAN ETIK
Nomor : 238/UN4.6.4.5.31/ PP36/ 2023

Tanggal: 14 April 2023

Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

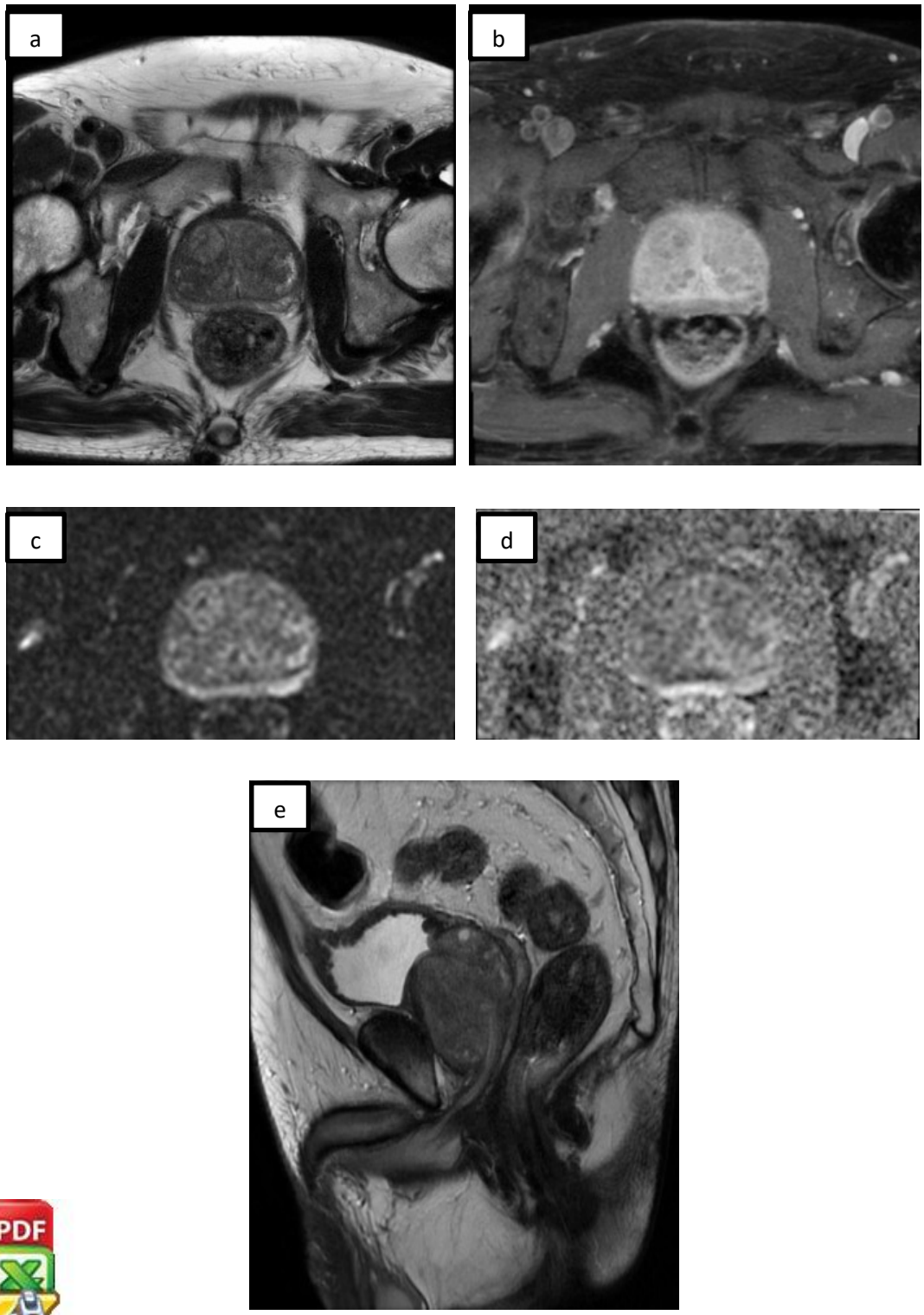
No Protokol	UH23030149	No Sponsor Protokol	
Peneliti Utama	**dr. Zida Maulina Aini**	Sponsor	
Judul Peneliti	AKURASI DIFFUSION-WEIGHTED IMAGING (DWI) MAGNETIC RESONANCE IMAGING (MRI) DIBANDINGKAN DENGAN DIGITAL RECTAL EXAMINATION (DRE) DAN PROSTATE SPESIFIC ANTIGEN (PSA) DALAM MENENTUKAN MALIGNANCY PROSTAT		
No Versi Protokol	**1**	Tanggal Versi	**1 Maret 2023**
No Versi PSP	**1**	Tanggal Versi	**1 Maret 2023**
Tempat Penelitian	RSUP Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	☐ Exempted ☒ Expedited ☐ Fullboard Tanggal	Masa Berlaku **14 April 2023** sampai **14 April 2024**	Frekuensi review lanjutan
Ketua KEP Universitas Hasanuddin	Nama **Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)**	Tanda tangan	
Sekretaris KEP Universitas Hasanuddin	Nama **dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)**	Tanda tangan	

Kewajiban Peneliti Utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Lapor SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

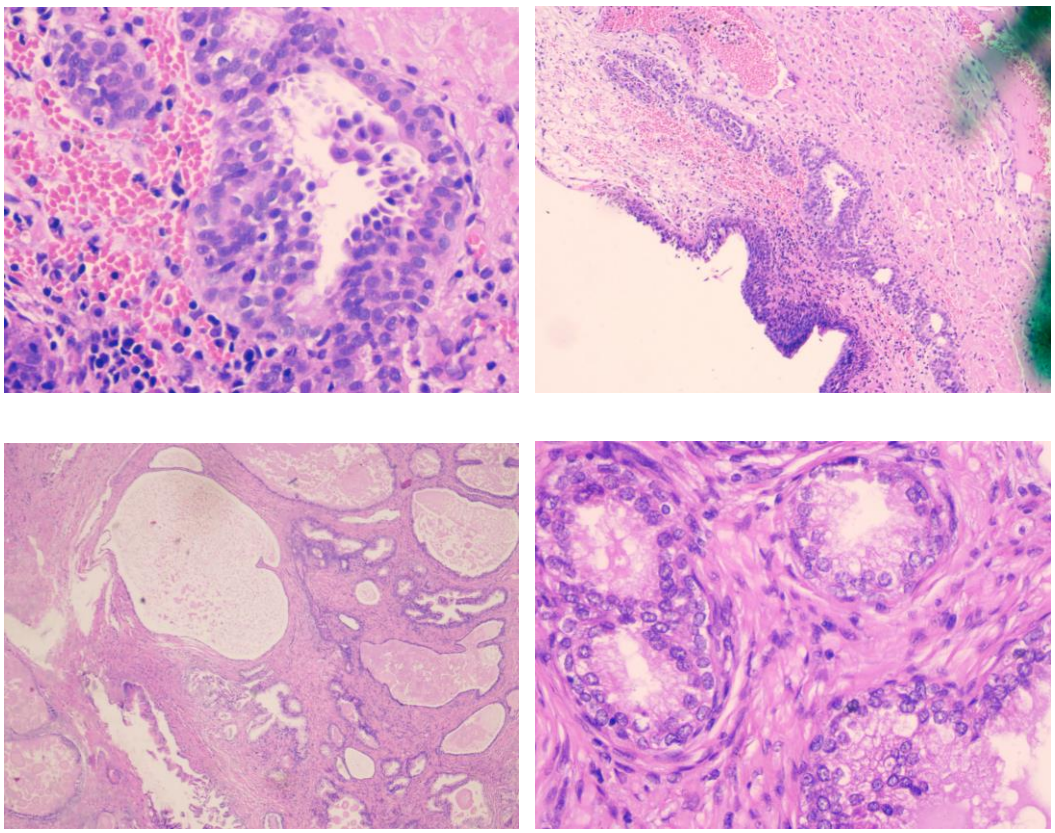
LAMPIRAN 2 Contoh Hasil Sampel Multiparametrik MRI prostat dan Histologi

Contoh Multiparametrik MRI prostat benign



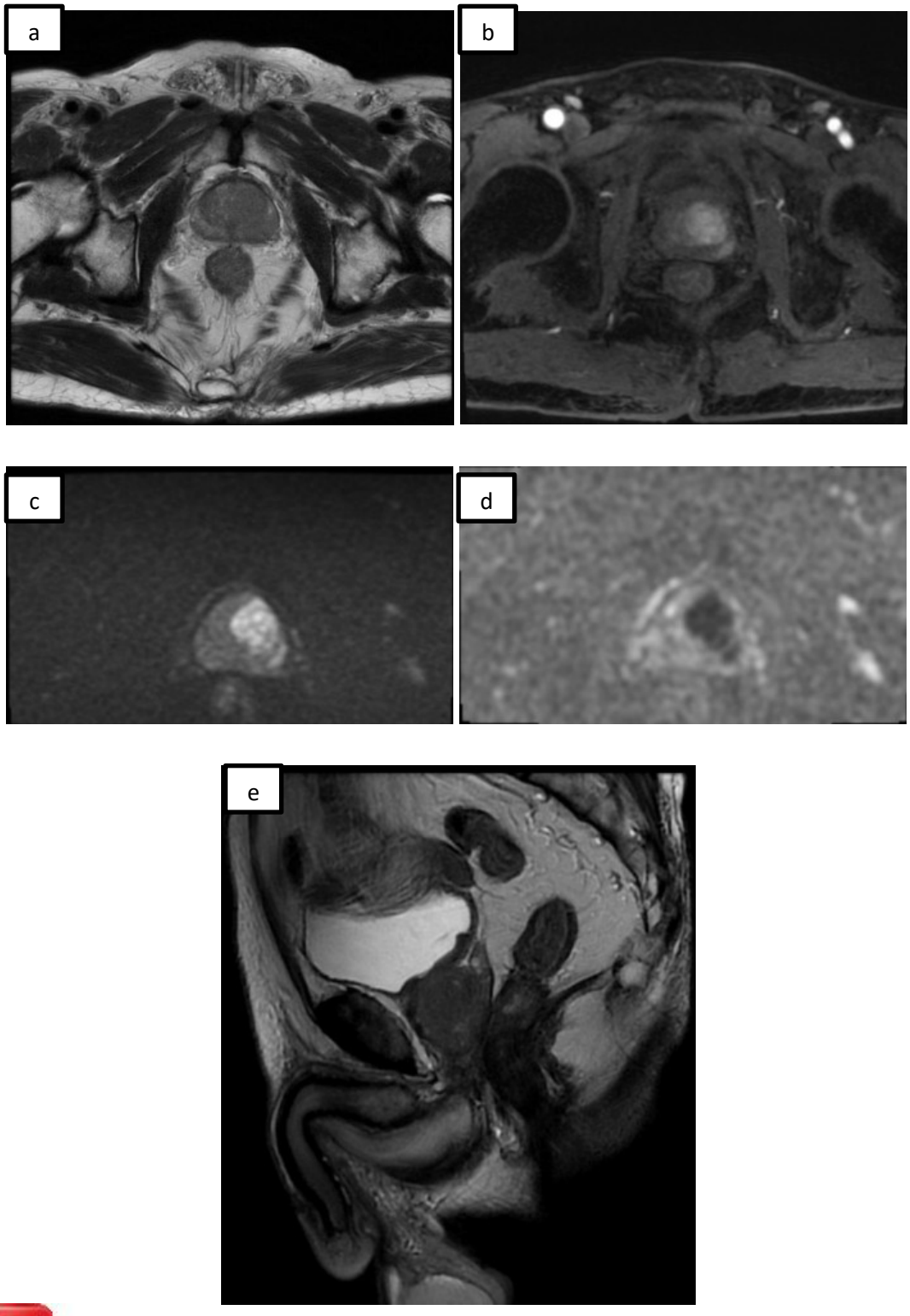
Merupakan gambar multiparametrik MRI prostat (a) potongan axial sequence T2WI tampak multiple lesi heterogen berkapsul pada zona trantitional bilateral, (b) potongan axial sequence DCE dengan level yang sama lesi tidak menyangat post kontras (-), (c,d) sequence DWI/ADC setinggi level yang sama tampak lesi yang non-restricted diffusion, dan (e) potongan sagittal sequence T2WI yang menunjukan lesi berada pada area basis, mid dan apex. Sehingga dapat disimpulkan terdapat lesi pada area base, mid dan apex zona transitional bilateral dengan PIRADS 2.

Hasil Histopatologi



Merupakan gambar mikroskopik sediaan jaringan asal prostat menunjukkan proliferasi kelenjar prostat diantara stroma fibromuskular yang proliferatif. Kelenjar prostat dilapisi sel epitel kuboid, inti tidak atipik, dengan sel basal masih intak. Sebagian lumen kelenjar berdilatasi kistik berisi corpora . Tampak pula infiltrasi sel-sel radang limfosit dan neutrofil padat pada an intraglandular. Kesimpulan Benign Prostat Hyperplasia dan prostatitis tif.

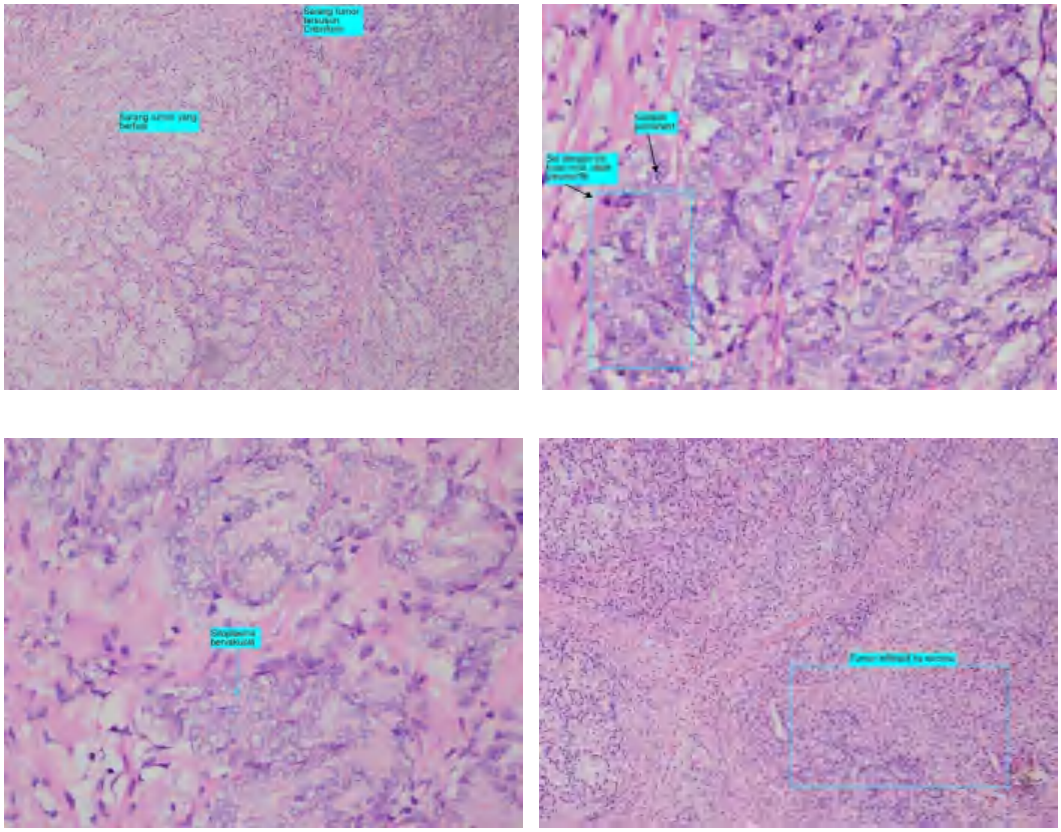
Contoh Multiparametrik MRI prostat Malignancy



erupakan gambar multiparametrik MRI prostat (a) potongan axial
ɛ T2WI tampak lesi hipointens homogen dengan diameter > 1.5 cm pada
ɪsitional sinistra, (b) potongan axial sequence DCE dengan level yang

sama tampak lesi yang menyangat post kontras (+), (c,d) sequence DWI/ADC setinggi level yang sama tampak lesi yang restricted diffusion, dan (e) potongan sagittal sequence T2WI yang menunjukan lesi berada pada area basis dan mid. Sehingga dapat disimpulkan terdapat lesi pada area base dan mid zona transitional sinistra dengan PIRADS 5.

Hasil Histopatologi



Merupakan gambar mikroskopik sediaan menunjukkan jaringan asal prostat yang terdiri dari proliferasi sel maligna asal kelenjar prostat, sebagian besar tersusun dengan pola cribriform (Gleason score 4) dan sebagian tampak kelenjar yang berfusi (Gleason score 4), tumbuh infiltratif ke stroma fibromuskular yang padat. Sarang tumor terdiri dari sel dengan inti bulat-oval, atipik, pleomorfik, hiperkromatik, nukleoli prominent, beberapa sitoplasma tampak bervakuol. Aktivitas mitosis 0-1/LPB. Tidak terdapat invasi sel tumor ke pembuluh ular pada sediaan ini. Total Gleason Score: 4+4=8 (WHO Grade Group npulannya Adenocarcinoma prostat (WHO GRADE GROUP IV)

LAMPIRAN 3 DATA DAN SAMPEL PENELITIAN

Kriteria_Umur

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	50-59	8	19.0	19.0	19.0
	60-69	19	45.2	45.2	64.3
	70-79	12	28.6	28.6	92.9
	>79	3	7.1	7.1	100.0
	Total	42	100.0	100.0	

DRE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	solid kenyal	13	31.0	31.0	31.0
	solid keras	29	69.0	69.0	100.0
	Total	42	100.0	100.0	

Kriteria_DRE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Benign	13	31.0	31.0	31.0
	Malignancy	29	69.0	69.0	100.0
	Total	42	100.0	100.0	

MRI

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	PIRADS 2	18	42.9	42.9	42.9
	PIRADS 3	5	11.9	11.9	54.8
	PIRADS 4	4	9.5	9.5	64.3
	PIRADS 5	15	35.7	35.7	100.0
	Total	42	100.0	100.0	

Kriteria_histologi

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Benign	21	50.0	50.0	50.0
	Malignancy	21	50.0	50.0	100.0
	Total	42	100.0	100.0	

Histologi

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	BPH	4	9.5	9.5	9.5
	BPH + Prostatitis kronik	16	38.1	38.1	47.6
	Gleason 3+3 = 6	5	11.9	11.9	59.5
	Gleason 3+4 = 7	5	11.9	11.9	71.4
	Gleason 4+3 = 7	2	4.8	4.8	76.2
	Gleason 4+4 = 8	3	7.1	7.1	83.3
	Gleason 4+5 = 9	2	4.8	4.8	88.1
	Gleason 5+3 = 8	1	2.4	2.4	90.5
	Gleason 5+4 = 9	1	2.4	2.4	92.9
	Gleason 5+5 = 10	2	4.8	4.8	97.6
	Stromal hyperplasia + Prostatis kronik	1	2.4	2.4	100.0
	Total	42	100.0	100.0	

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Kriteria_DRE * Kriteria_histologi	42	100.0%	0	0.0%	42	100.0%

Kriteria_DRE * Kriteria_histologi Crosstabulation

			Kriteria_histologi		
			Benign	Malignancy	Total
Kriteria_DRE	Benign	Count	13	0	13
		Expected Count	6.5	6.5	13.0
		% within Kriteria_DRE	100.0%	0.0%	100.0%
		% within Kriteria_histologi	61.9%	0.0%	31.0%
	Malignancy	Count	8	21	29
		Expected Count	14.5	14.5	29.0
		% within Kriteria_DRE	27.6%	72.4%	100.0%
		% within Kriteria_histologi	38.1%	100.0%	69.0%
Total		Count	21	21	42
		Expected Count	21.0	21.0	42.0
		% within Kriteria_DRE	50.0%	50.0%	100.0%
		% within Kriteria_histologi	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	18.828[a]	1	.000		
Continuity Correction[b]	16.042	1	.000		
Likelihood Ratio	24.062	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	18.379	1	.000		
N of Valid Cases	42				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.50.

b. Computed only for a 2x2 table

Kriteria_histologi

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Benign	21	50.0	50.0	50.0
	Malignancy	21	50.0	50.0	100.0
	Total	42	100.0	100.0	

Statistics

		Kriteria_histologi	Kriteria_PSA
N	Valid	42	42
	Missing	0	0
Mean		1.50	3.17
Median		1.50	3.50
Mode		1[a]	4
Std. Deviation		.506	.961
Minimum		1	1
Maximum		2	4
Sum		63	133

a. Multiple modes exist. The smallest value is shown

Kriteria_PSA

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 4	2	4.8	4.8	4.8
	4-10	10	23.8	23.8	28.6
	10-20	9	21.4	21.4	50.0
	> 20	21	50.0	50.0	100.0
	Total	42	100.0	100.0	

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	21.892[a]	3	.000
Likelihood Ratio	24.963	3	.000
Linear-by-Linear Association	18.810	1	.000
N of Valid Cases	42		

a. 4 cells (50.0%) have expected count less than 5. The minimum

:ount is 1.00.

Kriteria_DWI * Kriteria_histologi Crosstabulation

			Kriteria_histologi		
			Benign	Malignancy	Total
Kriteria_DWI	Benign	Count	14	0	14
		Expected Count	7.0	7.0	14.0
		% within Kriteria_DWI	100.0%	0.0%	100.0%
		% within Kriteria_histologi	66.7%	0.0%	33.3%
	Malignant	Count	7	21	28
		Expected Count	14.0	14.0	28.0
		% within Kriteria_DWI	25.0%	75.0%	100.0%
		% within Kriteria_histologi	33.3%	100.0%	66.7%
Total		Count	21	21	42
		Expected Count	21.0	21.0	42.0
		% within Kriteria_DWI	50.0%	50.0%	100.0%
		% within Kriteria_histologi	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	21.000[a]	1	.000		
Continuity Correction[b]	18.107	1	.000		
Likelihood Ratio	26.734	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	20.500	1	.000		
N of Valid Cases	42				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 7.00.

b. Computed only for a 2x2 table

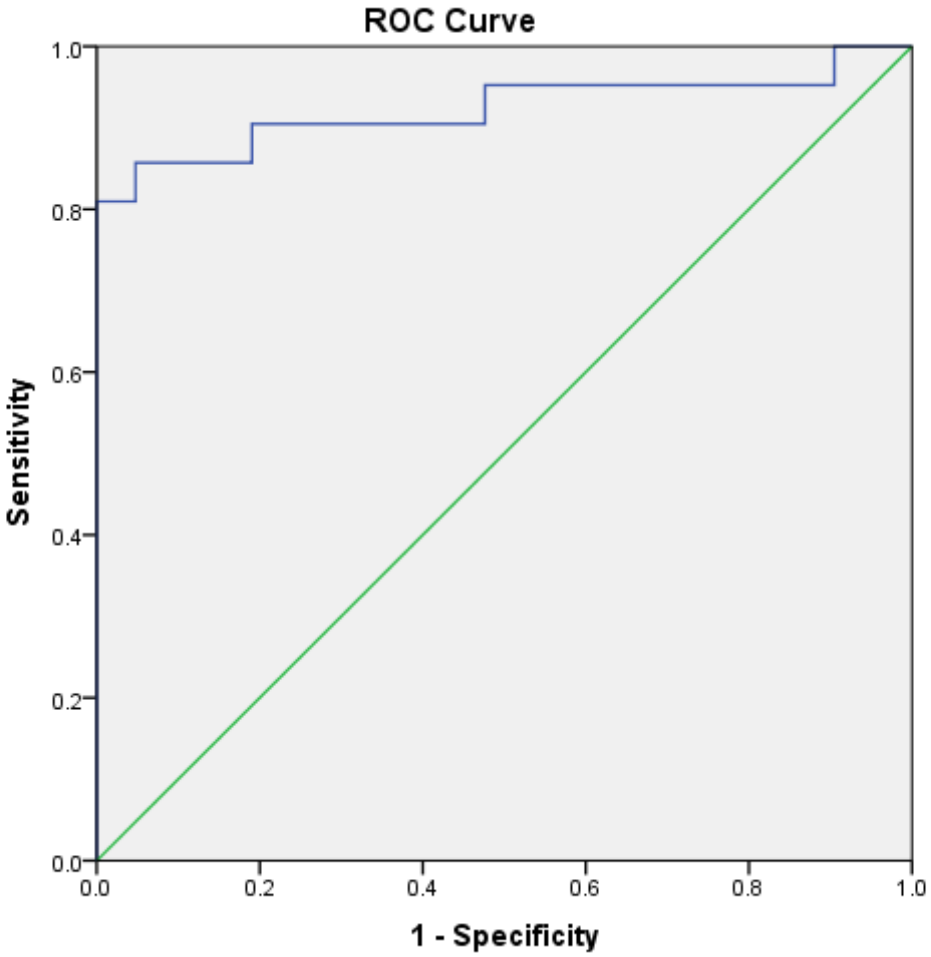
Area Under the Curve

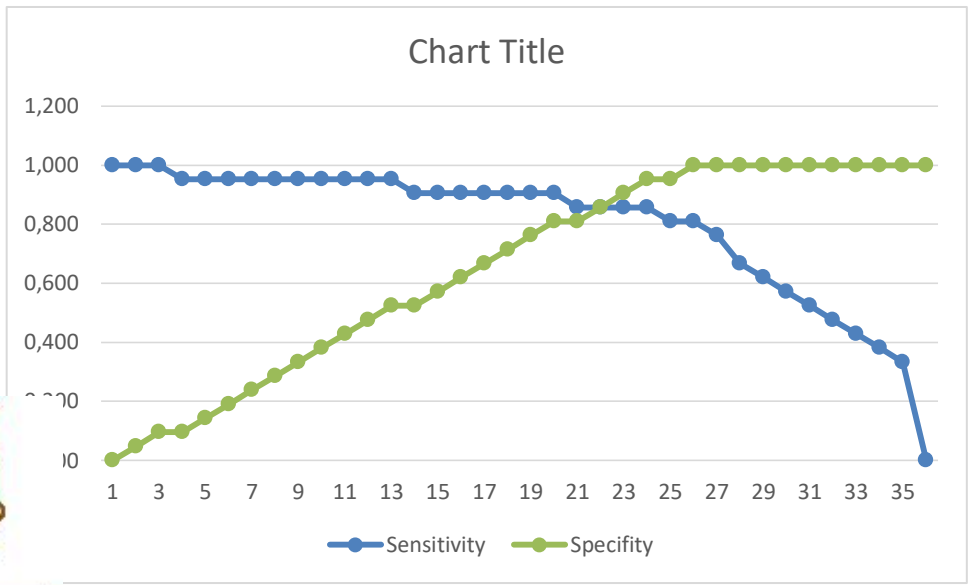
Test Result Variable(s): PSA

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
3	.048	.000	.828	1.000

ıe nonparametric assumption

othesis: true area = 0.5





Kriteria_Umur * Kriteria_histologi Crosstabulation

Count

		Kriteria_histologi		
		Benign	Malignancy	Total
Kriteria_Umur	50-59	1	7	8
	60-69	10	9	19
	70-79	9	3	12
	>79	1	2	3
Total		21	21	42

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	7.886[a]	3	.048
Likelihood Ratio	8.594	3	.035
Linear-by-Linear Association	3.296	1	.069
N of Valid Cases	42		

a. 4 cells (50.0%) have expected count less than 5. The minimum expected count is 1.50.

Kriteria_DWI * Kriteria_histologi Crosstabulation

Count

		Kriteria_histologi		
		Benign	Malignancy	Total
Kriteria_DWI	Benign	17	0	17
	Malignant	4	21	25
Total		21	21	42

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Nominal by Nominal	Contingency Coefficient	.636			.000
Interval	Pearson's R	.825	.076	9.220	.000[c]
Ordinal	Spearman Correlation	.825	.076	9.220	.000[c]
Cases		42			

uming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

c. Based on normal approximation.

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Kriteria_PSA_New * Kriteria_histologi	42	100.0%	0	0.0%	42	100.0%

Kriteria_PSA_New * Kriteria_histologi Crosstabulation

Count

		Kriteria_histologi		
		Benign	Malignancy	Total
Kriteria_PSA_New	< 24.9	18	3	21
	> 24.9	3	18	21
Total		21	21	42

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	21.429[a]	1	.000		
Continuity Correction[b]	18.667	1	.000		
Likelihood Ratio	23.775	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	20.918	1	.000		
N of Valid Cases	42				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 10.50.

b. Computed only for a 2x2 table

LAMPIRAN 4 CURRICULUM VITAE

A. Data Pribadi

- Nama : dr. Zida Maulina Aini, M.Ked.Trop
- Tempat/tanggal lahir : Kediri, 6 Agustus 1985
- Jenis Kelamin : Perempuan
- Alamat : Jalan Perintis Kemerdekaan IV Lorong 9 (belakang kost al Ikhlas 3), Tamalanrea, Kota Makassar
- Nama Ayah/Nama Ibu: Alm. Imam Maliki/Almh. Herniastuti
- Nama Suami : Ujang Hadisaputera, S.Pt
- Nama Anak : Nabila syafira putri

B. Riwayat Pendidikan

TK : TK Kusuma Mulia Wonorejo (1989-1991)

SD : SDN Manisrenggo Kota Kediri, Jawa Timur (1991-1996)

SMP : SMPN 3 Kediri, Jawa Timur (1997-2000)

SMA : SMU Negeri 2 Kediri, Jawa Timur (2000-2003)

S1 : Fakultas Kedokteran Universitas Hasanuddin (2003-2007)

Profesi : Pendidikan Dokter Universitas Hasanuddin (2007-2009)

S2 : Program Magister Ilmu Kedokteran Tropis Universitas Airlangga (2014-2016)

PPDS :Program Studi Radiologi Fakultas Kedokteran Universitas Hasanuddin Periode Juli 2020

C. Riwayat Pelatihan Tambahan :

- Pelatihan Pengembangan Keterampilan Dasar Teknik Instruksional (PEKERTI)
- Magang OSCE
- Multidiscipline Approach in Hepatobiliary Disease Primer design and advanced molecular technology
- Penyusunan SAP,Modul dan Skenario
- Seminar Pencegahan dan Penanganan DBD
- Seminar Sehari Penatalaksanaan Kegawatdaruratan Obstetri dalam Praktek Sehari-hari

  Seminar Review Mk Sistem Non Blok Mulok Kedokteran nutrisi Kelautan FK Unhalu

- Lokakarya Pengembangan Program Pendidikan Profesi
- Seminar Ilmiah “Achieve Better Care with Beta Blocker, Ace Inhibitor And Calcium Channel Blocker For Optimization Of Antihypertensive
- Pelatihan PEKERTI
- Panitia Seminar nasional Integrated management of Dengue (Host, Agent, Vector)

D. Riwayat Penugasan Selama Menjadi Dosen :

- Sekretaris Program Studi Pendidikan Dokter FK UHO (2012-2013)
- Sekretaris Jurusan FK UHO (2014)
- Koordinator Program Studi Pendidikan Dokter (2017-2019)
- Ketua Jurusan Fakultas Kedokteran Universitas Halu Oleo (Jan-Juli 2020)