Multi-center breast DCE-MRI data and segmentations from patients in the I-SPY 1/ACRIN 6657 trials (ISPY1)

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Summary

ACRIN 6657 was designed as a prospective study to test MRI for ability to predict response to treatment and risk-of-recurrence in patients with stage 2 or 3 breast cancer receiving neoadjuvant chemotherapy (NACT). **ACRIN 6657** was conducted as a companion study to CALGB 150007, a correlative science study evaluating tissue-based biomarkers in the setting of neoadjuvant treatment of breast cancer. Collectively, CALGB 150007 and ACRIN 6657 formed the basis of the multicenter **I**nvestigation of **S**erial Studies to **P**redict **Y**our **T**herapeutic **R**esponse with **I**maging and mo**L**ecular **A**n alysis (I-SPY TRIAL) breast cancer trial, a study of imaging and tissue-based biomarkers for predicting pathologic complete response (pCR) and recurrence-free survival (RFS). Additional information about the trial is available in the Stu dy Protocol and Case Report Forms. Participant Eligibility and Enrollment: Criteria for inclusion were patients enrolling on CALGB 150007 with T3 tumors measuring at least 3 cm in diameter by clinical exam or imaging and receiving neoadjuvant chemotherapy with an anthracycline-cyclophosphamide regimen alone or followed by a taxane. Pregnant patients and those with ferromagnetic prostheses were excluded from the study. The study was open to enrollment from May 2002 to March 2006. 237 patients were enrolled, of which 230 met eligibility criteria.

Acknowledgements

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Data Access

Data Access

Data Type	Download all or Query/Filter	License
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DICOM Metadata Digest (CSV, 1.54 MB)	*Download*	CC BY 3.0
Clinical and Outcome Data (CSV, 76 kB)	*Download*	CC BY 3.0

The ISPY team has provided additional options for download. The significance and download links for these subsets are explained under Detailed Description.

Click the Versions tab for more info about data releases.

Additional Resources for this Dataset

The NCI Cancer Research Data Commons (CRDC) provides access to additional data and a cloud-based data science infrastructure that connects data sets with analytics tools to allow users to share, integrate, analyze, and visualize cancer research data.

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- Imaging Data Commons (IDC) (Imaging Data)

Third Party Analyses of this Dataset

TCIA encourages the community to publish your analyses of our datasets. Below is a list of such third party analyses published using this Collection:

- Expert tumor annotations and radiomic features for the ISPY1/ACRIN 6657 trial data collection (ISPY1-Tumor-SEG-Radiomics)
- SDTM datasets of clinical data and measurements for selected cancer collections to TCIA (DI-Cubed-Reports)
- DICOM SR of clinical data and measurement for breast cancer collections to TCIA (DICOM-SR-Breast-Clinical)

Detailed Description

Detailed Description

Collection Statistics	
Modalities	MR, SEG
Number of Participants	222
Number of Studies	847
Number of Series	9032
Number of Images	386,528
Images Size (GB)	76.2

Requirements for MR imaging (As specified in the ACRIN 6657 protocol)

Imaging time points: MRI exams were performed within four weeks prior to starting anthracycline-cyclophosphamide chemotherapy (T1, MRI_1), at least 2 weeks after the first cycle of AC and prior to the second cycle of AC (T2, MRI_2), between anthracycline-cyclophosphamide treatment and taxane therapy if taxane was administered (T3, MRI_3), and after the final chemotherapy treatment and prior to surgery (T4, MRI_4). The study schema is shown in Figure 1



Figure 1. CALGB 150007 and ACRIN 6657 study schema.

Imaging protocol: MR imaging was performed on a 1.5 Tesla field strength scanner using a dedicated breast radiofrequency coil. The image acquisition protocol included a localization scan and T2-weighted sequence followed by a contrast-enhanced T1-weighted series. All imaging was performed unilaterally over the symptomatic breast and in the sagittal orientation. The contrast-enhanced series consisted of a high resolution (1mm in-plane spatial resolution) three-dimensional, fat-suppressed, T1-weighted gradient echo sequence with TR20 ms, TE = 4.5 ms, flip angle 45º, 16-18 cm field-of-view, minimum matrix 256x192, 64 slices, slice thickness 2.5 mm. Scan time length for the T1-weighted sequence was required to be between 4.5 and 5 minutes. The sequence was acquired once before contrast injection and repeated at least twice following injection.

Tumor diameter measurement and volumetric analysis: Tumor longest diameter (LD) was measured by the site radiologist as the greatest extent of disease on baseline MR images, including intervening areas of non-enhancing tissue. The same measurement direction was used on all subsequent MRI exams. The primary predictor variable, functional tumor volume (FTV) was measured from contrast-enhanced images using the signal enhancement ratio (SER) method. Volumetric analysis, including Quality Control assessment, was performed centrally at the Breast Imaging Research Program (BIRP) laboratory at University of California at San Francisco (UCSF).

Detailed information about the DICOM data is available in the DICOM Dictionary .

Further information on these studies can be found at:

- ACRIN 6657 Protocol http://www.acrin.org/6657_protocol.aspx
- CALGB 150007 http://www.cancer.gov/clinicaltrials/search/view?cdrid=69280&version=HealthProfessional

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Imaging Data Transfer History

The processing of the MR image data for ACRIN 6657 consisted of the following steps between image acquisition and the creation of this shared data set on TCIA:

- MRI studies were sent from the study centers to the ACRIN Core Lab either via media (DVD) or the TRIAD program
- Image data were de-identified and centrally archived at the ACRIN Core Lab
- Archived data was sent to the Breast Imaging Research Program (BIRP) at the University of California, San Francisco (UCSF) for volumetric analysis.
- De-identified image data, derived analysis maps and segmentations, and ancillary data files were transferred from UCSF to TCIA for data sharing.

While every effort was made to preserve the integrity of both the original image data and image meta-data (DICOM attributes, public and private), multiple file transfers and strict adherence to HIPPA guidelines for patient confidentiality may have resulted in loss of some data. If any questions arise, or patient PHI is found in any data on this collection, please contact the UCSF Breast Imaging Research Program (BIRP). For scientific or other inquiries about this dataset, please contact TCIA's Helpdesk.

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Curated Data Sets

In addition to the complete set of ACRIN 6657 imaging studies ("Level 0" data), the following curated data sets based on UCSF QC assessment, protocol compliance and data completeness are provided:

- Level 1: MRI Longest Diameter (LD)
- Level 2a: SER Volume Dataset for ongoing volumetric analyses (updated 9/17/16)
- Level 2b: SER Volume Dataset for pCR Analysis (Hylton, et al; Radiology 2012)
- Level 3: SER Volume Dataset for RFS Analysis (Hylton, et al; Radiology, 2016)

The image data sets are accompanied by Excel files with selected patient clinical and outcome data.

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Data subset Descriptions

Data set	subjects	All Series	DCE + Derived Only	DCE Only	Clinical and outcome data
Level 0: Complete image data set	222	Download (76.2 GB)	NA	NA	Download
Level 1: Studies with MRI LD measurements	219	Download (75 GB)	NA	NA	Download
Level 2a: Studies with SER Volume measurements	207	Download (63 GB)	Download (4 3 GB)	Download (24 GB)	Download
Level 3: Studies used in primary aim analysis	162	Download (49 GB)	Download (3 4 GB)	Download (18 GB)	Download

Level 0: Complete I-SPY 1 / ACRIN 6657 MRI Dataset

This data set is comprised of all HIPPA compliant, DICOM compliant MRI series.

Level 0 image data set consists of 847 on-study MRI studies on 222 subjects in the UCSF image database.
One patient in the image data collection (I-SPY ID 1079) does not appear in the Feb. 2, 2011 I-SPY FINAL LOCKED clinical data dump. So no clinical or outcome data is available for this subject.

Level 1: MRI exams for which longest diameter was measured

This data set is comprised of all studies with MRI measured longest diameter (LD) values reported.
839 MRI studies have LD reported in the I-SPY 1 clinical database, of which 5 studies are not present in either the UCSF or ACRIN image data collections (see Table 1).
Level 1 image data set consists of **834 MRI studies on 219 subjects** in the UCSF image database

Table 1. Studies that have LD measurement but are missing from the UCSF and ACRIN TRIAD image data collections:		
ID 1071, T1 ID 1138, T1	ID 1101, T3 ID 1040, T4	ID 1187, T4

Level 2a: Good SER Volume Dataset – updated 9/3/14, 9/17/16

This data set is comprised of the patient studies which, following quality reviews in 2014 and 2016, were judged to have sufficiently good image quality and protocol compliance for volumetric DCE SER analysis. Rejection criteria included: incomplete volumetric DCE acquisitions, lack of a 2nd post-contrast acquisition, variability in fat suppression across the image, observed patient motion during the DCE acquisition, significant DCE protocol deviations such as changing scan parameters or image position during DCE acquisition.

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Level 2a image data set consists of **706 MR studies on 207 subjects** in the UCSF image database. These include 7 studies not included in Level 1 (no MRI LD recorded) as listed in Table 2.

Table 2. Studies in Level 2a (good volumetric analysis) that do NOT have LD measures:		
ID 1059, T4 ID 1079, T2 * ID 1104, T4	ID 1192, T2 ID 1212, T4	ID 1215, T1 ID 1238, T2

- Patient 1079 does not appear in the Feb. 2, 2011 I-SPY FINAL LOCKED clinical data set. So no clinical or outcome data is available.

Level 2b: SER Volume Dataset Reported in Hylton et al. (Radiology, 2012) *

This data set is comprised of the patient studies analyzed for pCR outcome and reported in the 2012 Radiology paper on ACRIN 6657 pCR results *. This data set is not provided as a shared list, as it is not recommended for use in further analysis. It is described here because it is the data set from which the Level 3 (primary aim analysis) set was derived. Inclusion and exclusion was determined by quality and protocol reviews available at that time. In addition to the exclusion criteria listed for Level 2a, studies done with imaging in the axial plane, in violation of the sagittal orientation specified in the trial imaging protocol, were excluded due to processing limitations of the analysis software. Similarly, bi-lateral sagittal acquisitions (alternating left and right volumetric acquisitions) were excluded.

Level 2b image data set consists of **707 MRI studies on 207 subjects** in the UCSF image database.

- Hylton, N. M., Blume, J. D., Bernreuter, W. K., Pisano, E. D., Rosen, M. A., Morris, E. A., Weatherall, P. T., Lehman, C. D., Newstead, G. M., Polin, S., Marques, H. S., Esserman, L. J., & Schnall, M. D. (2012). *Locally Advanced Breast Cancer: MR Imaging for Prediction of Response to Neoadjuvant Chemotherapy—Results from ACRIN 6657/I-SPY TRIAL*. https://doi.org/10.1148/radiol.12110748 PMC3359517

Tables 3 and 4 show the specific inclusion/exclusion differences between Levels 2a and 2b:

Table 3. 16 studies accepted for SER analysis since 2008 (in Level 2a but not in 2b)		
ID 1005, T3 ID 1043, T2 ID 1046, T4 ID 1057, T3 ID 1074, T3 ID 1084, T1	ID 1110, T4 ID 1139, T4 ID 1159, T4 ID 1176, T2 ID 1201, T2	ID 1203, T4 ID 1206, T4 ID 1225, T3 ID 1219, T3 ID 1228, T4

Table 4. 17 studies rejected since 2008 (in Level 2b but not in 2a)	
Study ID and TP	**Reason for rejection for volumetric SER analysis (level 2a)**
1007 T4 *	No fatSat; Different protocol from T1
1035 T4 *	Only 1 post scan then acq. parameters changed
1045 T1	Alternating laterality acquisitions, 2 minute time gap

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1047 T1 *	Image position changed during DCE
1053 T2 *	Alternating laterality acquisitions, bad pre- acquisition
1053 T4 *	Alternating laterality acquisitions
1055 T1 *	Alternating laterality acquisitions, 4 minute time gap
1086 T1 *	Alternating laterality acquisitions, time gap, different protocol from T4
1091 T1 *	Changing acq. parameters during DCE
1095 T2 *	Only 1 post scan then acq. parameters changed
1173 T3 *	Off protocol timing
1206 T1	Bad DCE timing, 20 minute delay
1206 T2	Bad DCE timing, 1'29" acquisition time
1224 T3 *	Scan position changed during DCE
1230 T3 *	Scan position changed during DCE
#128 T1, T2	2 studies for ineligible patient: ACRIN ID 128 (no I-SPY ID)

- Subjects that *were* included in the primary aim analysis (Level 3)

Level 3: Subset of Level 2b used in primary aim analysis, reported in Hylton et al. (Radiology, 2016) *

This data set is comprised of the patient studies analyzed for RFS outcome and reported in the 2015 Radiology paper on ACRIN 6657 survival results (Hylton et al, Radiology *). Table 5 shows the 45 patients excluded from the level 2a cohort for this analysis. Please see the publication for specific information on exclusions of patients from this group.

Level 3 image data set consists of **586 MRI studies on 162 subjects** in the UCSF image database. This is also the study cohort used as the Test Phase data in the QIN BMMR Challenge.

Table 5. 45 subjects excluded from Level 2b set

ID 1027	ID 1079	ID 1157	ID 1182	ID 1210	ID 1234
ID 1040	ID 1084	ID 1159	ID 1185	ID 1212	ID 1235
ID 1045	ID 1103	ID 1160	ID 1187	ID 1214	ID 1237
ID 1046	ID 1110	ID 1167	ID 1189	ID 1215	ID 1238
ID 1048	ID 1120	ID 1171	ID 1192	ID 1219	
ID 1054	ID 1137	ID 1176	ID 1194	ID 1221	ineligible:
ID 1063	ID 1139	ID 1177	ID 1203	ID 1222	Case #: 128
ID 1067	ID 1152	ID 1180	ID 1206	ID 1228	

- Hylton, N. M., Gatsonis, C. A., Rosen, M. A., Lehman, C. D., Newitt, D. C., Partridge, S. C., Bernreuter, W. K., Pisano, E. D., Morris, E. A., Weatherall, P. T., Polin, S. M., Newstead, G. M., Marques, H. S., Esserman, L. J., & Schnall, M. D. (2016). Neoadjuvant Chemotherapy for Breast Cancer: Functional Tumor Volume by MR Imaging Predicts Recurrence-free Survival—Results from the ACRIN 6657/CALGB 150007 I-SPY 1 TRIAL. https://doi.org/10.1148/radiol.2015150013 PMC4819899

Citations & Data Usage Policy

Citations & Data Usage Policy

Users must abide by the TCIA Data Usage Policy and Restrictions. Attribution should include references to the following citations:

Data Citation

David Newitt, Nola Hylton, on behalf of the I-SPY 1 Network and ACRIN 6657 Trial Team. (2016). **Multi-center breast DCE-MRI data and segmentations from patients in the I-SPY 1/ACRIN 6657 trials.** The Cancer Imaging Archive. https://doi.org/10.7937/K9/TCIA.2016.HdHpgJLK

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Data publicly released and new "level-specific" download options provided.

Version 1: Updated 2015/06/18

Data Type	Download all or Query/Filter
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